Santé Canada Health Canada

Biologic and Radiopharmaceutical Drugs Directorate

Drug Submission Performance Quarterly Report

October - December

2021

Canada

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Également disponible en français sous le titre :
Direction des médicaments biologiques et radiopharmaceutiques - Rapport trimestriel du rendement des présentations de drogue - octobre - décembre 2021

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Publication date: March 2022

Cat H162-5E-PDF
ISSN 2563-6723
Pub 210625

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OVERVIEW

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD) Quarterly Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive quarters: from October - December 2020 to October - December 2021. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

Several significant events occurred during the spring of 2020 including the COVID-19 Pandemic and the implementation of revised fees in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*.

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately in 2019, HPFB had implemented new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format. [1] This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.

- An Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was approved and on August 13, 2020 the Minister of Health approved the Order respecting certain time limits under the Food and Drug Regulations temporarily extending the default period to review clinical trial applications and amendments from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. The order extending the default period expired on November 16, 2020. The number of CTA and CTA-As received under orders are included in this report.

- The Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (ISAD Interim Order) was approved by the Governor in Council on September 25, 2020. This interim order was introduced, in part, to create a new authorization pathway to help expedite the authorization of drugs and vaccines for COVID-19. The number of applications and amendments filed, the number of applications and amendments in review, and the number of authorizations issued under the ISAD Interim Order are included in this report.

[1] The Regulatory Enrolment Process (REP) and the Common Electronic Submissions Gateway (CESG)

- On April 1, 2020, revised fees were implemented in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124).* In addition, safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as a Notifiable Change) for submissions based only on clinical or non-clinical data.

- Decisions made in 2020-2021 included submissions filed under both the pre-2020 and post-2020 cost recovery framework.

- The *Food and Drug Regulations* have been amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs to receive an NOC through a new drug submission (NDS). The amendments maintain some of the mechanisms introduced through the Interim order respecting the importation, sale and advertising of drugs for use in relation to COVID-19 (ISAD IO), thus continuing to provide Canadians with quick access to safe and effective COVID-19 drugs. The "NDS CV" submission type has been created for NDSs that use any of the provisions in subsections C.08.002(2.1), C.08.002(2.2) or C.08.002(2.3) of the *Regulations*. Additional information can be found at https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/food-drug-regulations-amendments-covid-19.html.

General Information

There are several steps involved in the drug submission review[2] and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

Submissions Received are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions "under active review" on the last day of the quarter. **"Backlog"** is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

Approvals[3] are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

Authorization means an authorization issued under section 5 of the ISAD Interim Order.

A **review cycle completion**[4] is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken to complete a cycle (excluding any pause days[5]) is compared to a set performance standard which is based on the type of submission, class and cycle (status).

Performance for all submissions or applications filed after April 1, 2020 is tracked individually.

[2] For further clarification, refer to the Guidance for Industry: Management of Drug Submissions.

[3] Final results from confirmatory trials submitted in the form of an SNDS-C are included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures. For further clarification, refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

[4] Review cycles include all types e.g. Review 1, Review 2, Review QN, Review Post JR. The total number of "review decisions" may surpass the total number of review cycle completions as they include cancellations/withdrawals that occur while the submission is 'inactive'. For example, a withdrawal can be issued when a company fails to respond to a notice of non-compliance within the allotted time frame. A 'Cancelled by Company' is counted as a review decision when a company sends a cancellation letter after the submission's original materials have been accepted for review.

[5] In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance (effective date: April 1, 2020).

"First Cycle Review" Approvals are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude "refiled"[6] submissions.

Biosimilar is a biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

Any questions or comments on this report should be forwarded to:

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[6] For further clarification refer to the Guidance for Industry: Management of Drug Submissions.

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
COV19	-	Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
COV19A	-	Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application - Amendment
DINA	-	Application for a Drug Identification Number for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard
DINB	-	Application for a Drug Identification Number for a biological product
DIND	-	Application for a Drug Identification Number for a disinfectant product
DINF	-	Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	-	Abbreviated Extraordinary Use New Drug Submission
EUNDS	-	Extraordinary Use New Drug Submission
EUSANDS	-	Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	-	Supplement to an Extraordinary Use New Drug Submission
MPNDS	-	Pre-Submission Meeting New Drug Submission
MPSNDS	-	Pre-Submission Meeting Supplement to a New Drug Submission
NC	-	Notifiable Change
NDS	-	New Drug Submission
NDS-CV		New Drug Submission - for Designated COVID-19 Drugs
NDS-D	-	New Drug Submission for Disinfectant products
PDC	-	Post-authorization Division 1 Change for a pharmaceutical product
PDC-B	-	Post-authorization Division 1 Change for a biologic drug product

PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission
SANDS	-	Supplement to an Abbreviated New Drug Submission
SANDS-C	-	Supplement to an Abbreviated New Drug Submission - Confirmatory
SNDS	-	Supplement to a New Drug Submission
SNDS-C	-	Supplement to a New Drug Submission - Confirmatory
SNDS-D	-	Supplement to a New Drug Submission for Disinfectant products
YBPR	-	Yearly Biologic Product Report

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with Conditions
IO_NOA	-	Notice of Authorization
IO_NOA_TC	-	Notice of Authorization with Terms and Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patented Medicines (NOC) Regulations
Issuable NOC (Rx to OTC)	-	NOC on Hold due to changes (Prescription to Non-Prescription)
NON	-	Notice of Non-Compliance
NOD	-	Notice of Deficiency
NON Withdrawal	-	Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	-	Notice of Deficiency Withdrawal Letter

Fee Categories

Fee Category	Description
New active substance	Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph
Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance
Clinical or nonclinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance
Comparative studies	Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance
Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance
Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance
Switch status from prescription drug to non-prescription drug	Submissions based only on data that support the modification or removing of a medicinal ingredient listed in Schedule F of the Food and Drug Regulations (i.e. identical claim for existing drug) - Category discontinued
Labelling only	Submissions, other than those described in item 9, 12 or 13, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data)

Fee Category	Description
Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment
Administrative submission	Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the Food and Drugs Act)
Disinfectant – full review	Submissions, other than those described in item 12, that include data in support of a disinfectant
Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacture's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug
Drug identification number application - labelling standards	Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data
Published data only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance - Category discontinued

For further information, please consult the Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications.

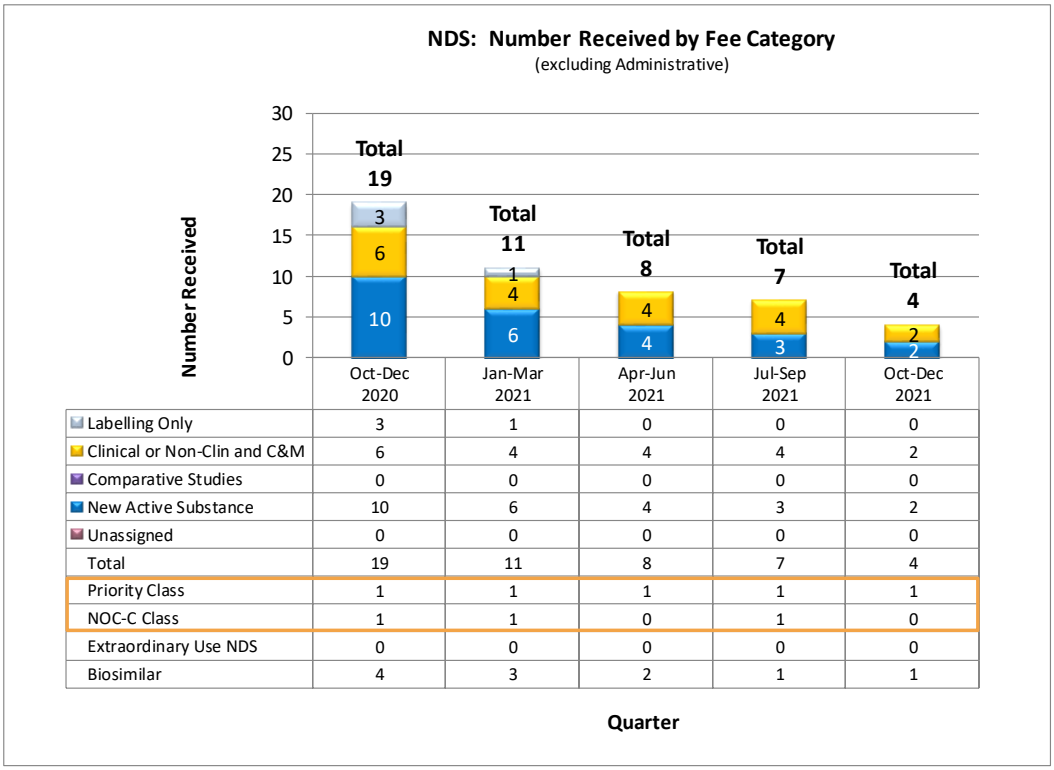
New Drug Submissions (NDS)

&

Supplemental New Drug Submissions (SNDS)

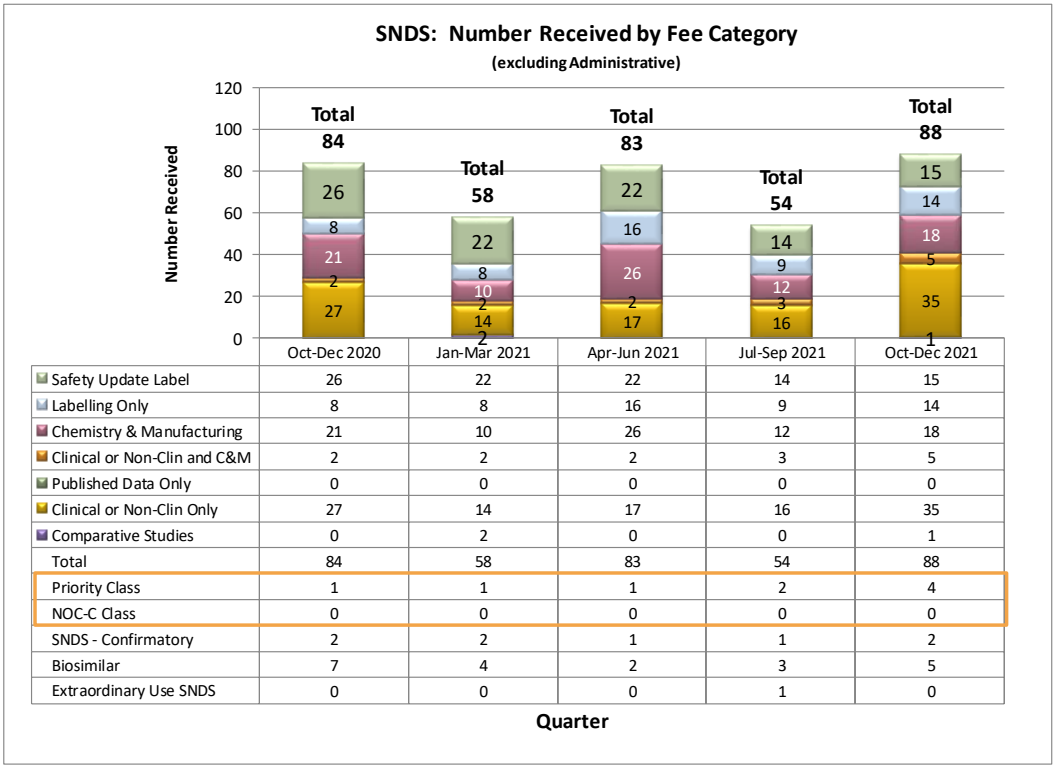
SUBMISSIONS RECEIVED [7]

NDS: Received by Fee Category



	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Labelling Only	3	1	0	0	0
Clinical or Non-Clin and C&M	6	4	4	4	2
Comparative Studies	0	0	0	0	0
New Active Substance	10	6	4	3	2
Unassigned	0	0	0	0	0
Total	19	11	8	7	4
Priority Class	1	1	1	1	1
NOC-C Class	1	1	0	1	0
Extraordinary Use NDS	0	0	0	0	0
Biosimilar	4	3	2	1	1

SNDS: Received by Fee Category

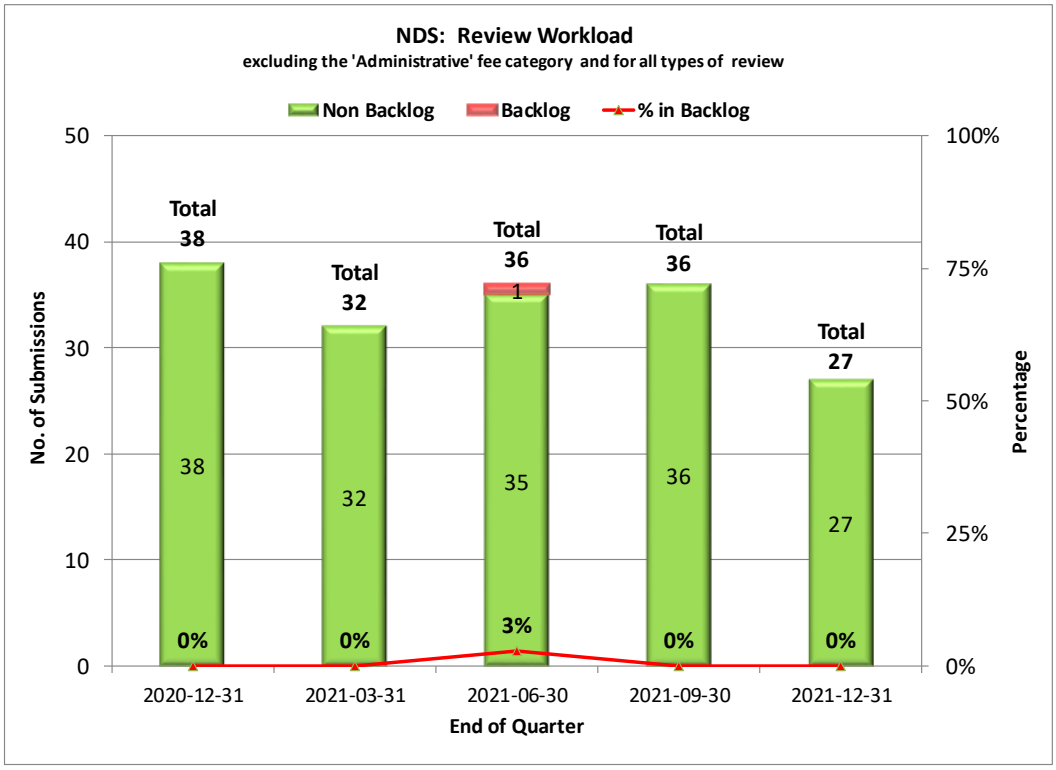


	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Safety Update Label	26	22	22	14	15
Labelling Only	8	8	16	9	14
Chemistry & Manufacturing	21	10	26	12	18
Clinical or Non-Clin and C&M	2	2	2	3	5
Published Data Only	0	0	0	0	0
Clinical or Non-Clin Only	27	14	17	16	35
Comparative Studies	0	2	0	0	1
Total	84	58	83	54	88
Priority Class	1	1	1	2	4
NOC-C Class	0	0	0	0	0
SNDS - Confirmatory	2	2	1	1	2
Biosimilar	7	4	2	3	5
Extraordinary Use SNDS	0	0	0	1	0

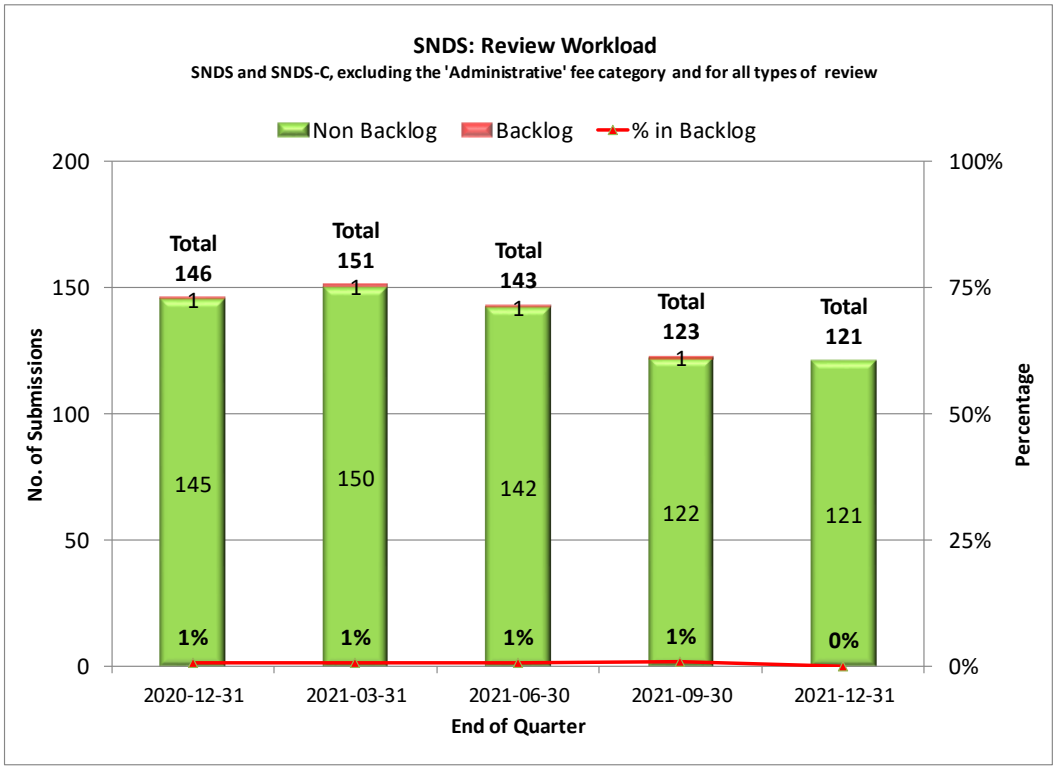
[7] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance.

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

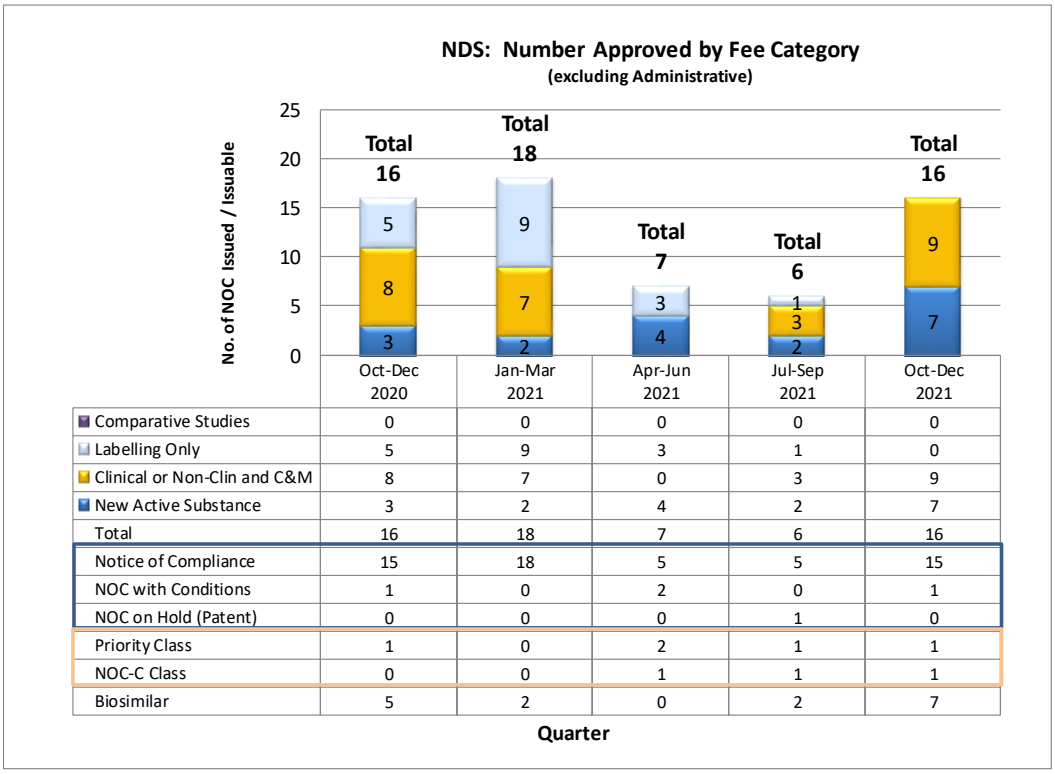
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Clinical or Non-Clin and C&M	14	14	17	19	13
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	13	14	18	17	14
Backlog	*0*	*0*	*1*	*0*	*0*
Labelling Only	11	4	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	38	32	36	36	27
Non Backlog	38	32	35	36	27
Backlog	0	0	1	0	0
% in Backlog	0%	0%	3%	0%	0%
Priority (subset)	2	3	2	2	2
Backlog	*0*	*0*	*0*	*0*	*0*

SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Comparative Studies	0	2	2	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	26	31	30	25	26
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	78	75	65	57	53
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	6	5	7	5	10
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	8	13	12	17	13
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	28	25	27	19	19
Backlog	*1*	*1*	*1*	*1*	*0*
Total	146	151	143	123	121
Non Backlog	145	150	142	122	121
Backlog	1	1	1	1	0
% in Backlog	1%	1%	1%	1%	0%
Priority (subset)	1	2	1	2	4
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	5	5	7	6	3
Backlog	*0*	*0*	*0*	*0*	*0*

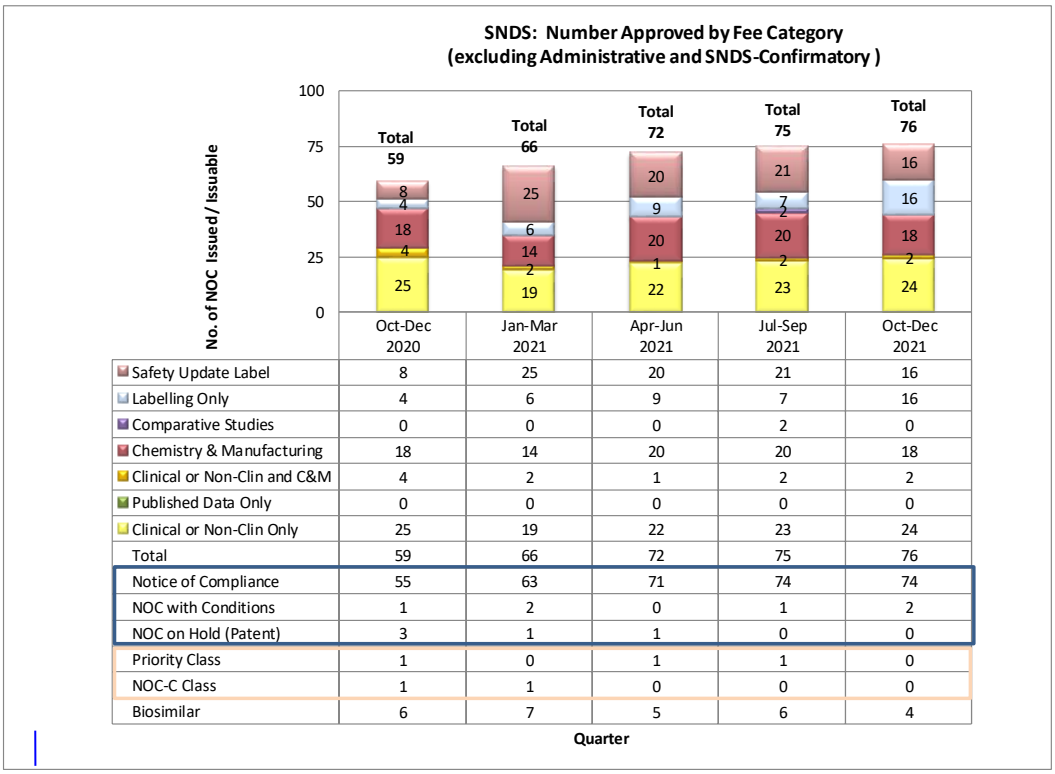
APPROVALS [8]

NDS: Number Approved by Fee Category and NOC Type



	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Comparative Studies	0	0	0	0	0
Labelling Only	5	9	3	1	0
Clinical or Non-Clin and C&M	8	7	0	3	9
New Active Substance	3	2	4	2	7
Total	16	18	7	6	16
Notice of Compliance	15	18	5	5	15
NOC with Conditions	1	0	2	0	1
NOC on Hold (Patent)	0	0	0	1	0
Priority Class	1	0	2	1	1
NOC-C Class	0	0	1	1	1
Biosimilar	5	2	0	2	7

SNDS: Number Approved by Fee Category and NOC Type



	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Safety Update Label	8	25	20	21	16
Labelling Only	4	6	9	7	16
Comparative Studies	0	0	0	2	0
Chemistry & Manufacturing	18	14	20	20	18
Clinical or Non-Clin and C&M	4	2	1	2	2
Published Data Only	0	0	0	0	0
Clinical or Non-Clin Only	25	19	22	23	24
Total	59	66	72	75	76
Notice of Compliance	55	63	71	74	74
NOC with Conditions	1	2	0	1	2
NOC on Hold (Patent)	3	1	1	0	0
Priority Class	1	0	1	1	0
NOC-C Class	1	1	0	0	0
Biosimilar	6	7	5	6	4

[8] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance.

BIOSIMILARS: NDS & SNDS Market Authorizations

Biosimilars: Number of Market Authorization for NDS & SNDS by Quarter

Submission Type	Class	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
NDS	CLIN/C&M	9	3	0	1	7
NDS Total		**9**	**3**	**0**	**1**	**7**
SNDS	C&M ONLY	3	4	2	2	2
	C&M/LABELLING	2	0	0	1	1
	CLIN ONLY	3	1	4	2	1
	CLIN/C&M	0	1	0	0	0
	COMP/C&M	0	0	0	0	0
	LABELLING ONLY	1	0	0	1	0
	SAFETY UPDATE LABEL	1	1	1	0	0
SNDS Total		**10**	**7**	**7**	**6**	**4**

Biosimilars: NDS Market Authorizations during FY 2021-22 (Apr 1 2021 - Mar 31 2022)

Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2021-22	Notice of Compliance (NOC) Date
ABEVMY	CLIN/C&M	BGP PHARMA ULC	BEVACIZUMAB	Q3	2021-Nov-5
AYBINTIO	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	BEVACIZUMAB	Q3	2021-Nov-30
AYBINTIO	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	BEVACIZUMAB	Q3	2021-Nov-30
BAMBEVI	CLIN/C&M	APOTEX INC.	BEVACIZUMAB	Q2	2021-Sep-23
IXIFI	CLIN/C&M	PFIZER CANADA ULC	INFLIXIMAB	Q3	2021-Dec-21
KIRSTY	CLIN/C&M	BGP PHARMA ULC	INSULIN ASPART	Q3	2021-Oct-12
NYPOZI	CLIN/C&M	TANVEX BIOPHARMA USA, INC	FILGRASTIM (R-METHUG-CSF)	Q3	2021-Oct-8
YUFLYMA	CLIN/C&M	CELLTRION HEALTHCARE CO LTD	ADALIMUMAB	Q3	2021-Dec-24
New Drug Submission Total					**8**

Biosimilars: SNDS Market Authorizations during FY 2021-22 (Apr 1 2021 - Mar 31 2022)

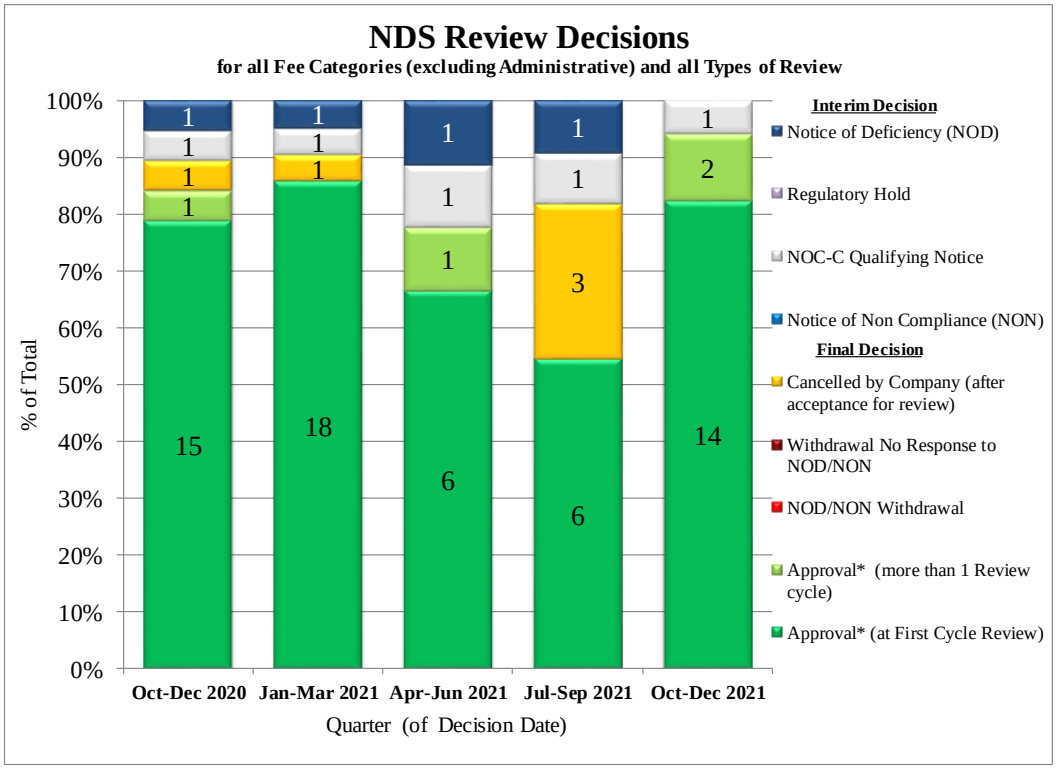
Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2021-22	Notice of Compliance (NOC) Date
AVSOLA	C&M ONLY	AMGEN CANADA INC	INFLIXIMAB	Q3	2021-Oct-27
ERELZI	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q1	2021-Jun-24
GRASTOFIL	CLIN ONLY	APOTEX INC.	FILGRASTIM (R-METHUG-CSF)	Q2	2021-Sep-29
FILGRASTIM (R-METHUG-CSF)	C&M ONLY	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q2	2021-Aug-4
HERZUMA	CLIN ONLY	CELLTRION HEALTHCARE CO LTD	TRASTUZUMAB	Q1	2021-Apr-16
HULIO	C&M ONLY	BGP PHARMA ULC	ADALIMUMAB	Q1	2021-May-14
HYRIMOZ	CLIN ONLY	SANDOZ CANADA INCORPORATED	ADALIMUMAB	Q2	2021-Sep-10
KANJINTI	CLIN ONLY	AMGEN CANADA INC	TRASTUZUMAB	Q1	2021-Apr-14
KANJINTI	LABELLING ONLY	AMGEN CANADA INC	ABP 980	Q2	2021-Jul-20
KANJINTI	C&M/LABELLING	AMGEN CANADA INC	ABP 980, TRASTUZUMAB	Q2	2021-Aug-4
LAPELGA	C&M/LABELLING	APOTEX INC.	PEGFILGRASTIM	Q3	2021-Dec-24
NYVEPRIA	C&M ONLY	PFIZER CANADA ULC	PEGFILGRASTIM	Q3	2021-Nov-9
OGIVRI	CLIN ONLY	BGP PHARMA ULC	TRASTUZUMAB	Q3	2021-Dec-6
OMNITROPE	C&M ONLY	SANDOZ CANADA INCORPORATED	SOMATROPIN	Q2	2021-Aug-11
RITUXIMAB	CLIN ONLY	SANDOZ CANADA INCORPORATED	RITUXIMAB	Q1	2021-Jun-30
TRAZIMERA	CLIN ONLY	PFIZER CANADA ULC	TRASTUZUMAB	Q1	2021-Apr-14
TRAZIMERA	SAFETY UPDATE LABEL	PFIZER CANADA ULC	TRASTUZUMAB	Q1	2021-Jun-18
Supplemental New Drug Submission				**TOTAL**	**17**

Please note: Approved Biosimilars that remain on Intellectual Property Hold are not included.

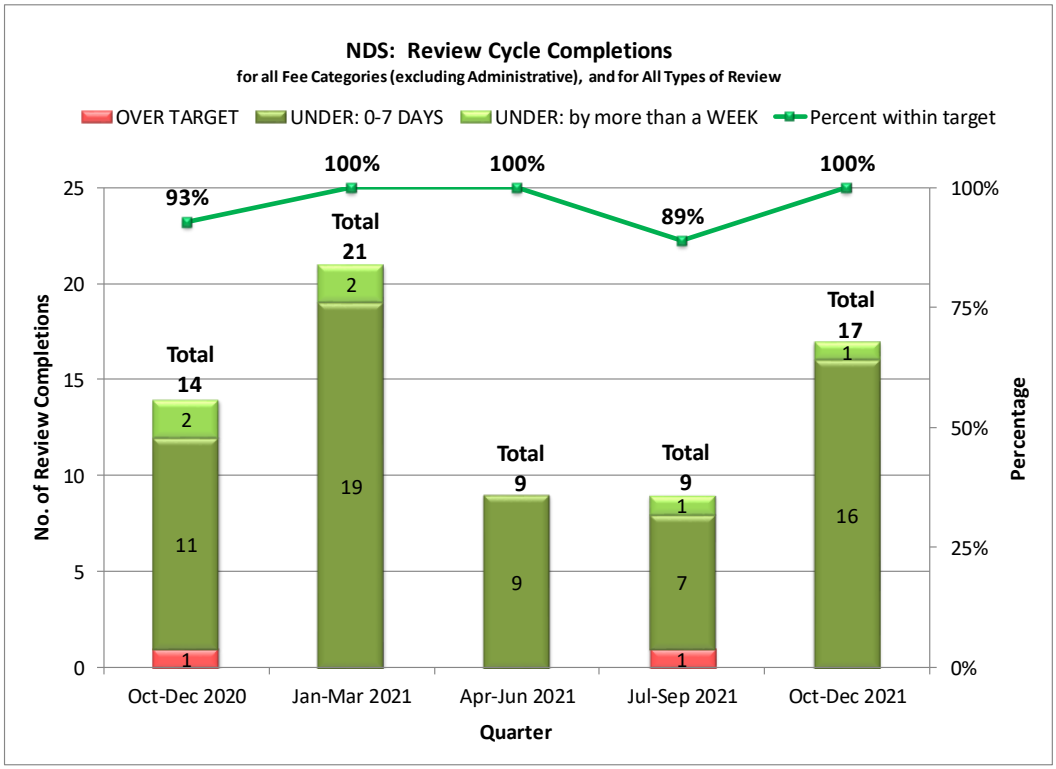
Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

REVIEW PERFORMANCE

NDS: Review Decisions by Type

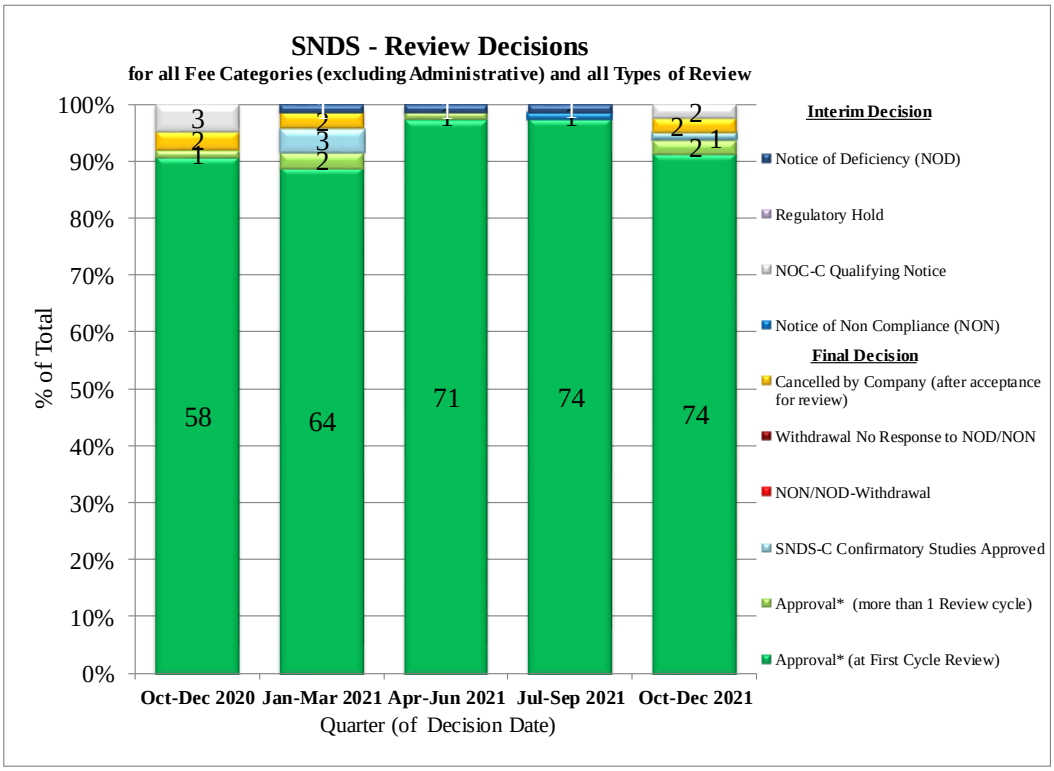


NDS: Review Cycle Completions

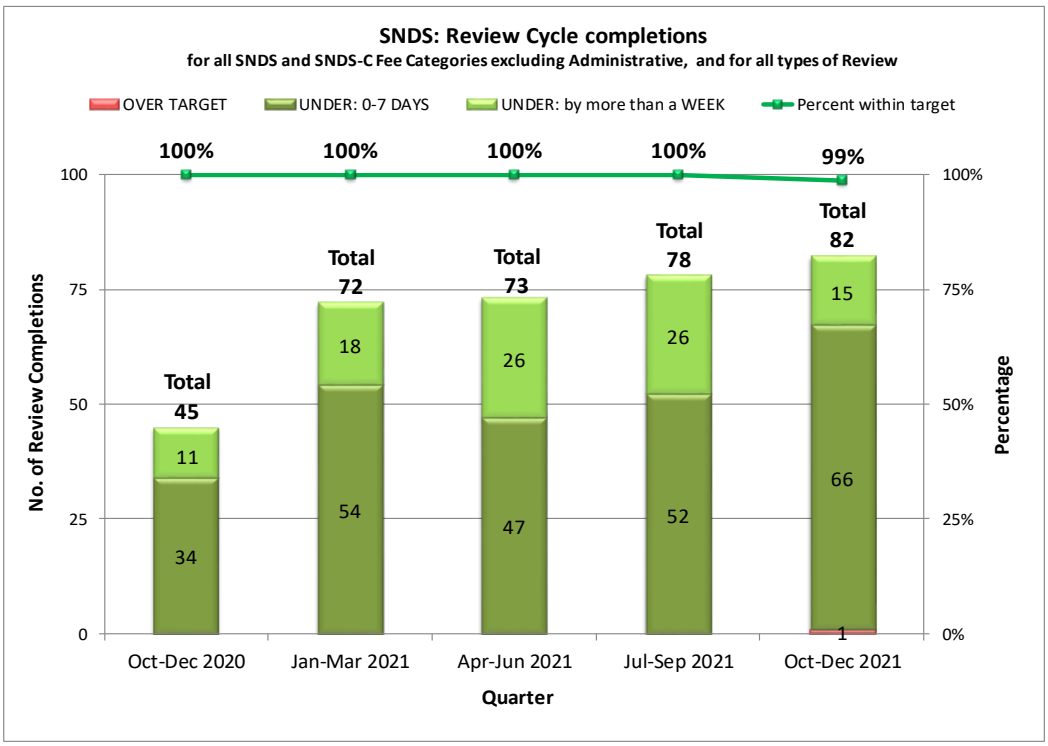


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

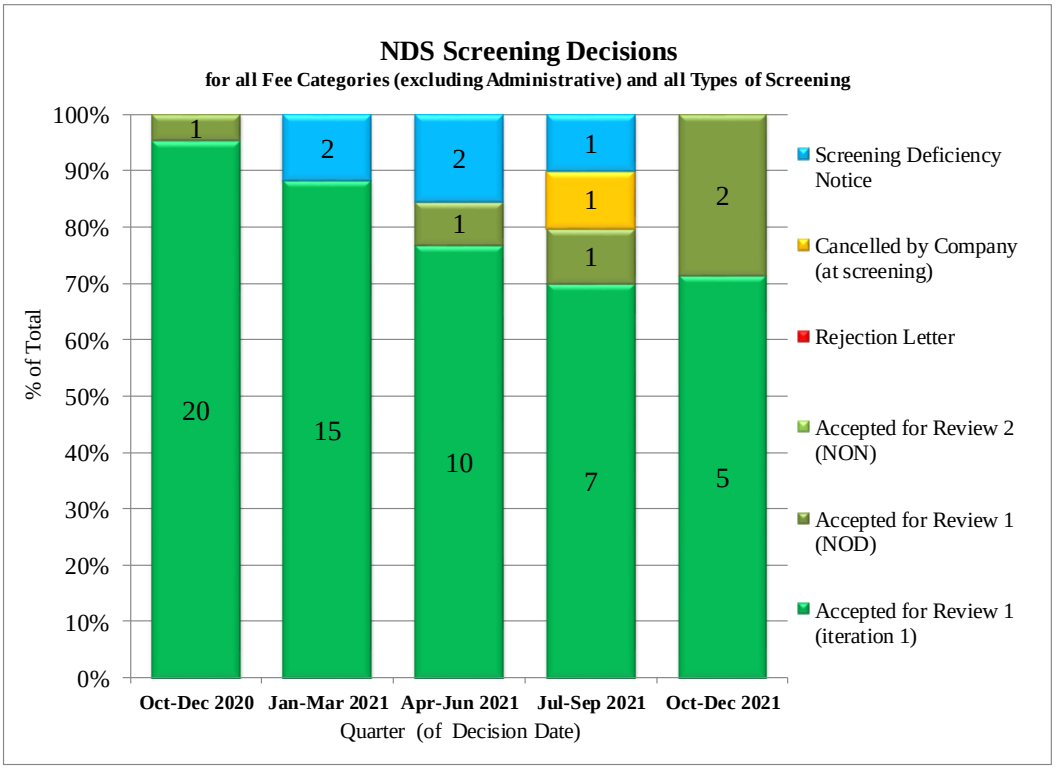


SNDS: Review Cycle Completions

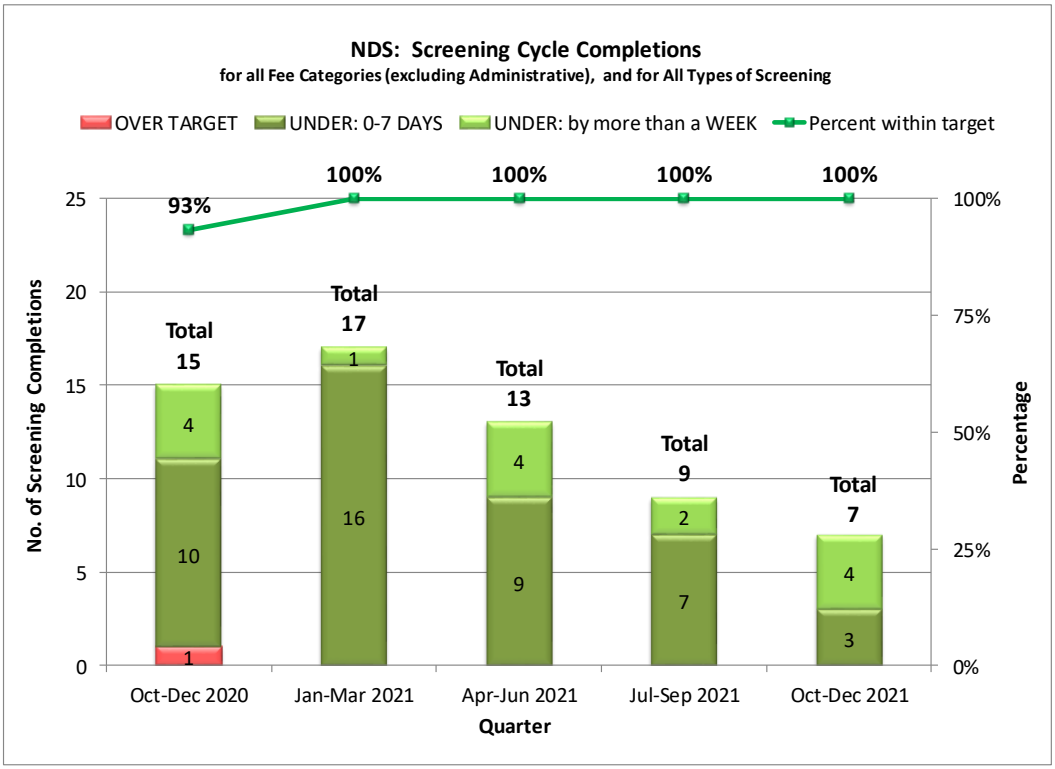


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

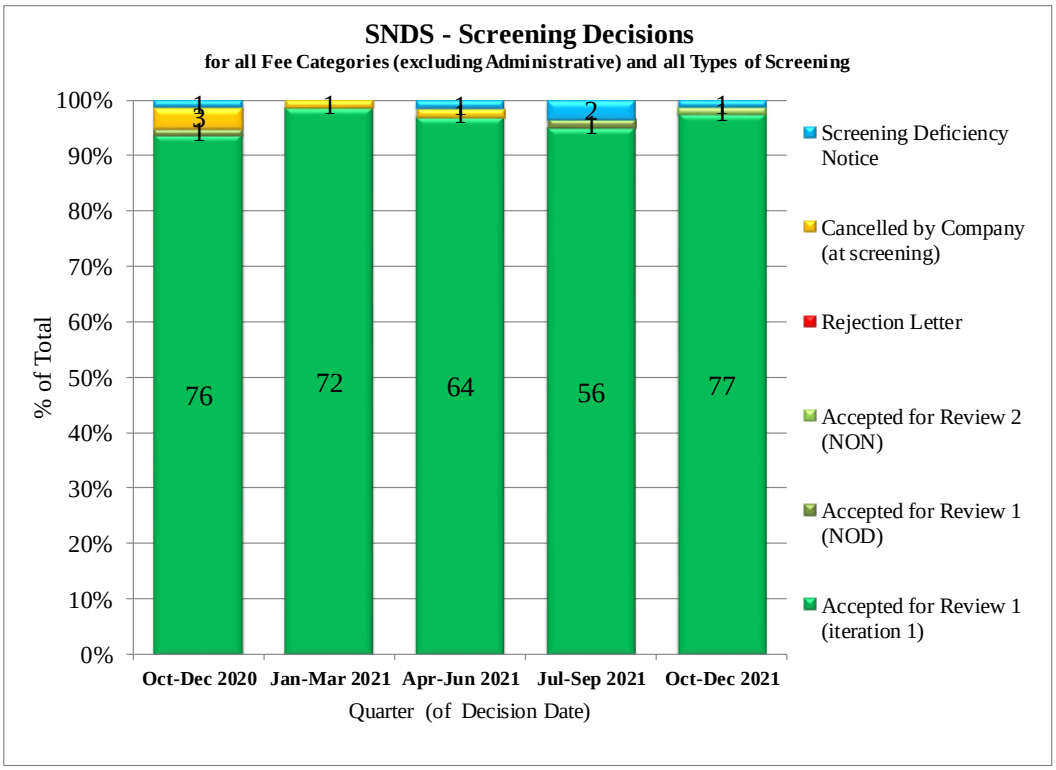


NDS: Screening Cycle Completions

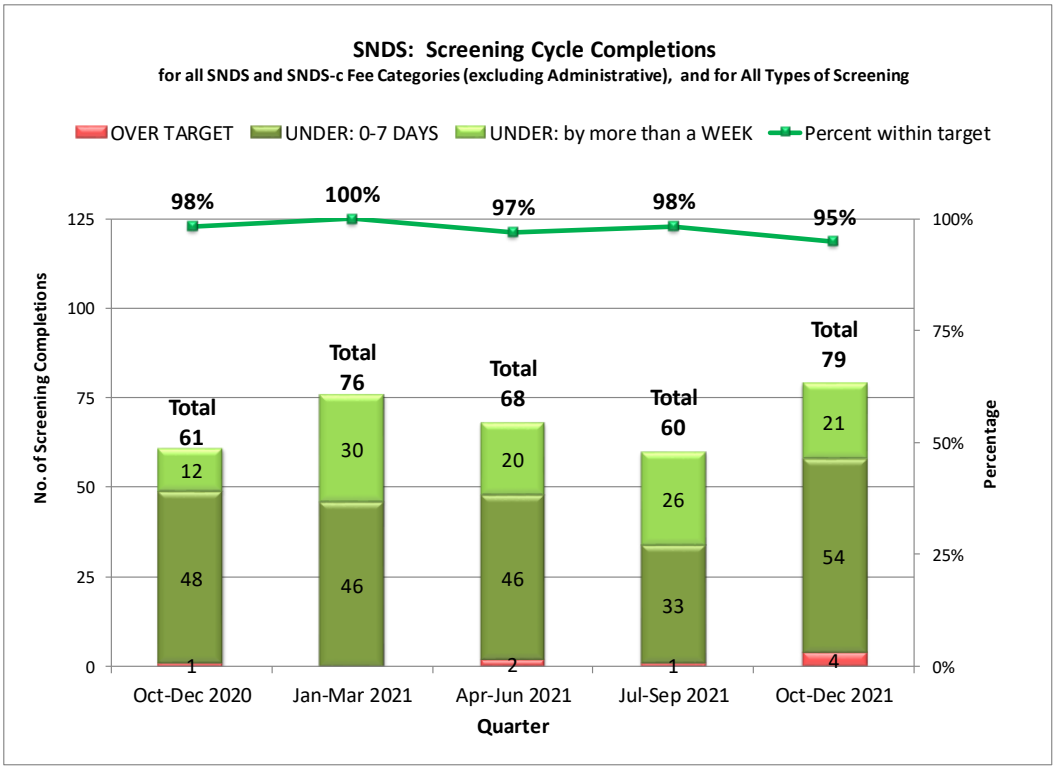


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type

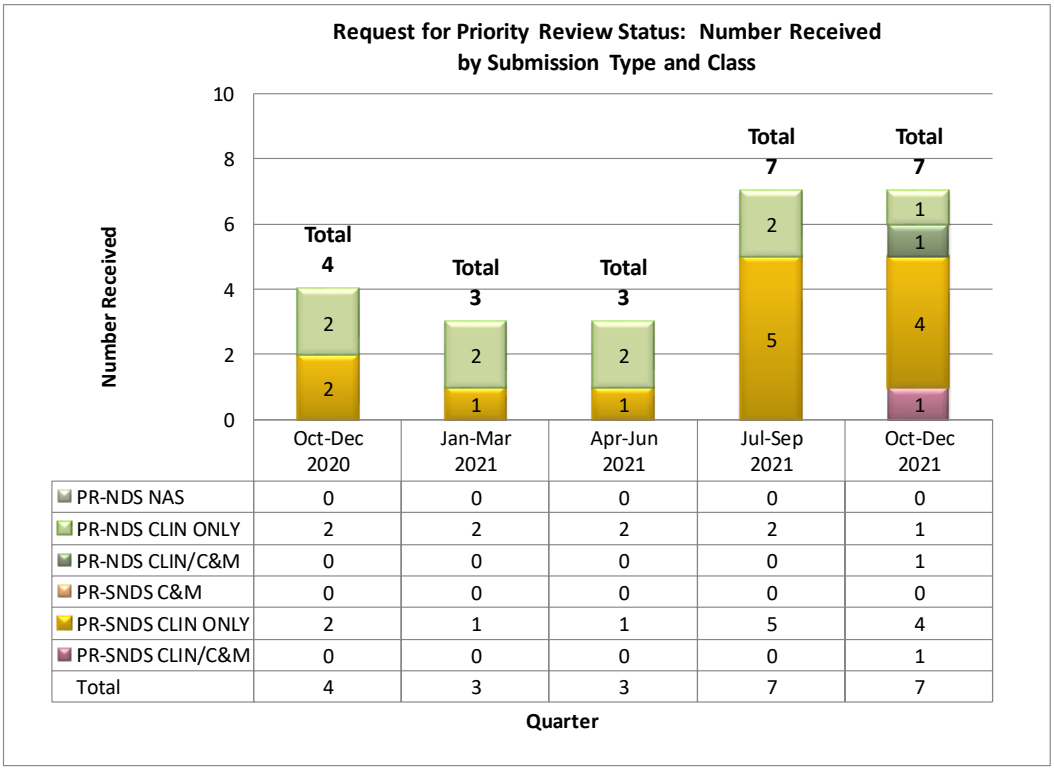


SNDS: Screening Cycle Completions



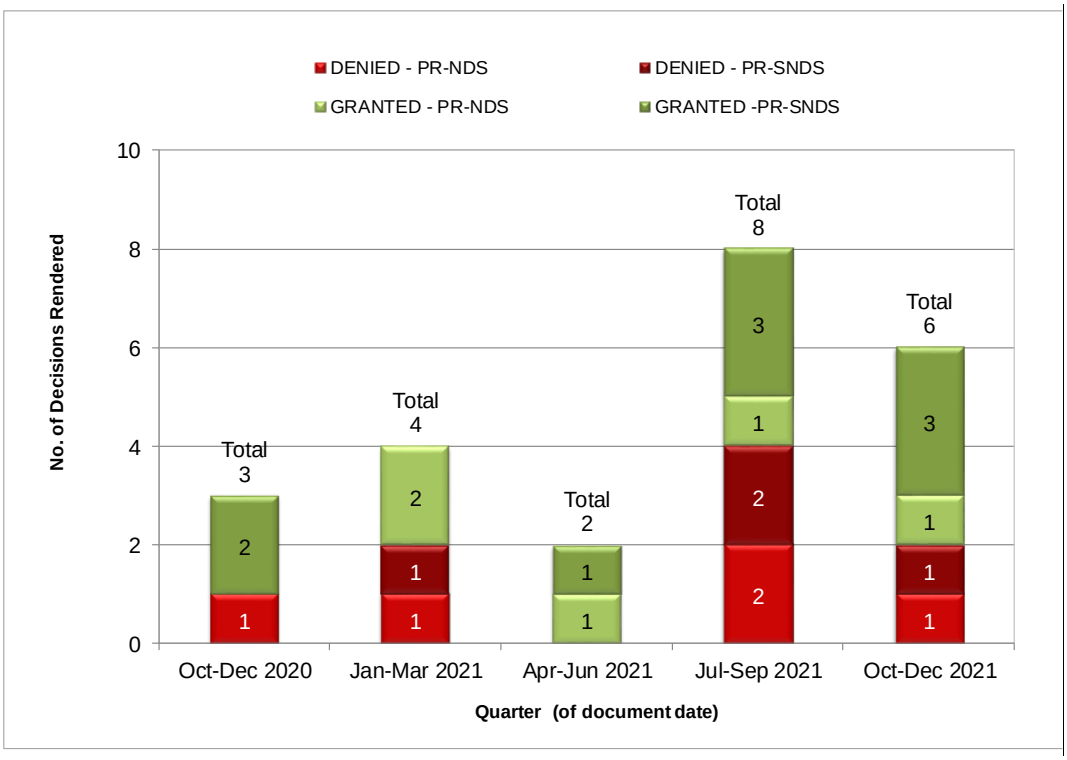
REQUEST FOR PRIORITY REVIEW STATUS (NDS & SNDS)

Request for Priority Review Status: Number Received

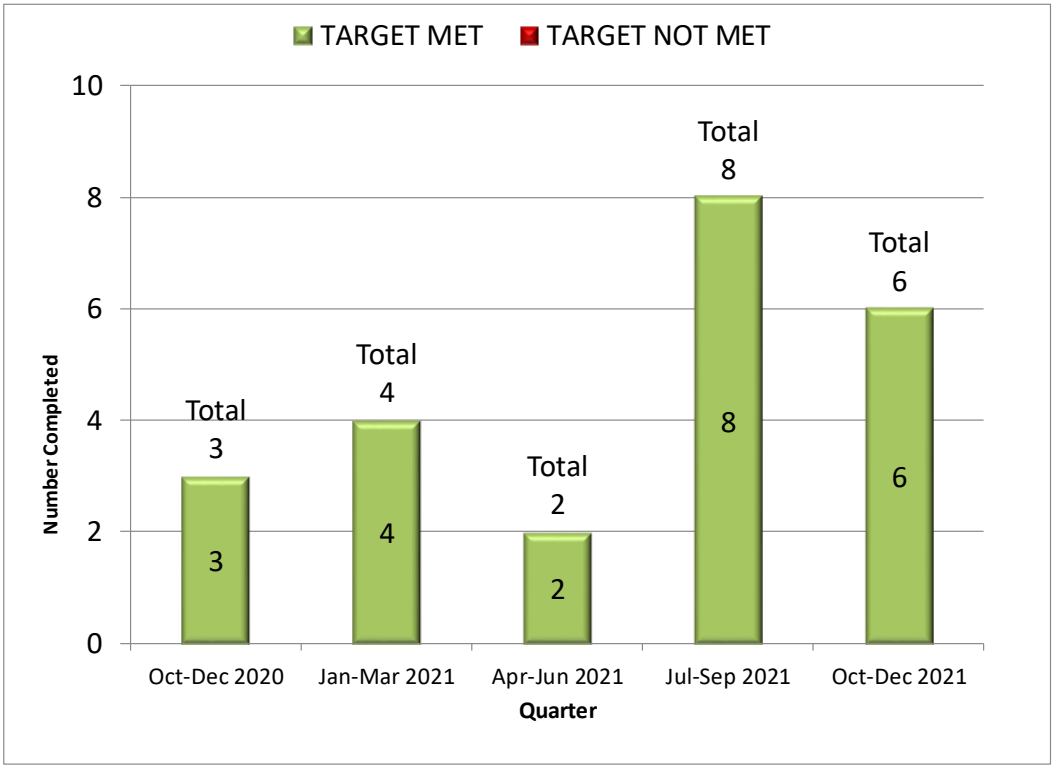


	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
PR-NDS NAS	0	0	0	0	0
PR-NDS CLIN ONLY	2	2	2	2	1
PR-NDS CLIN/C&M	0	0	0	0	1
PR-SNDS C&M	0	0	0	0	0
PR-SNDS CLIN ONLY	2	1	1	5	4
PR-SNDS CLIN/C&M	0	0	0	0	1
Total	4	3	3	7	7

Request for Priority Review Status: Decisions Rendered



Request for Priority Review Status: Performance



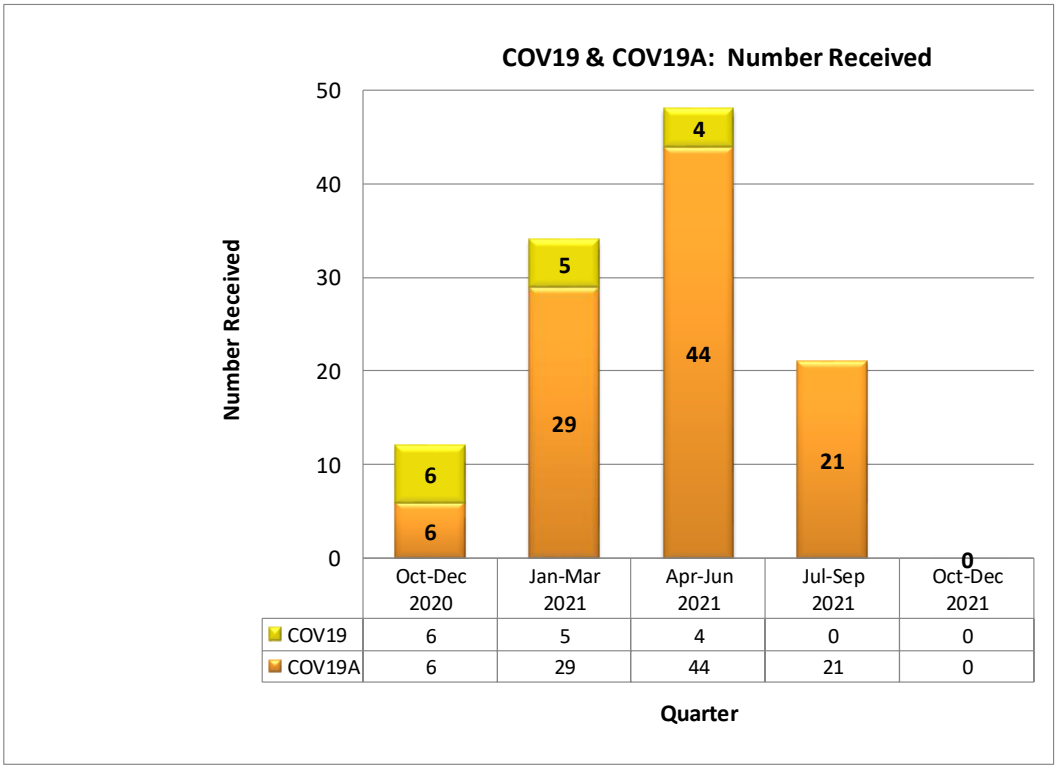
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19A)

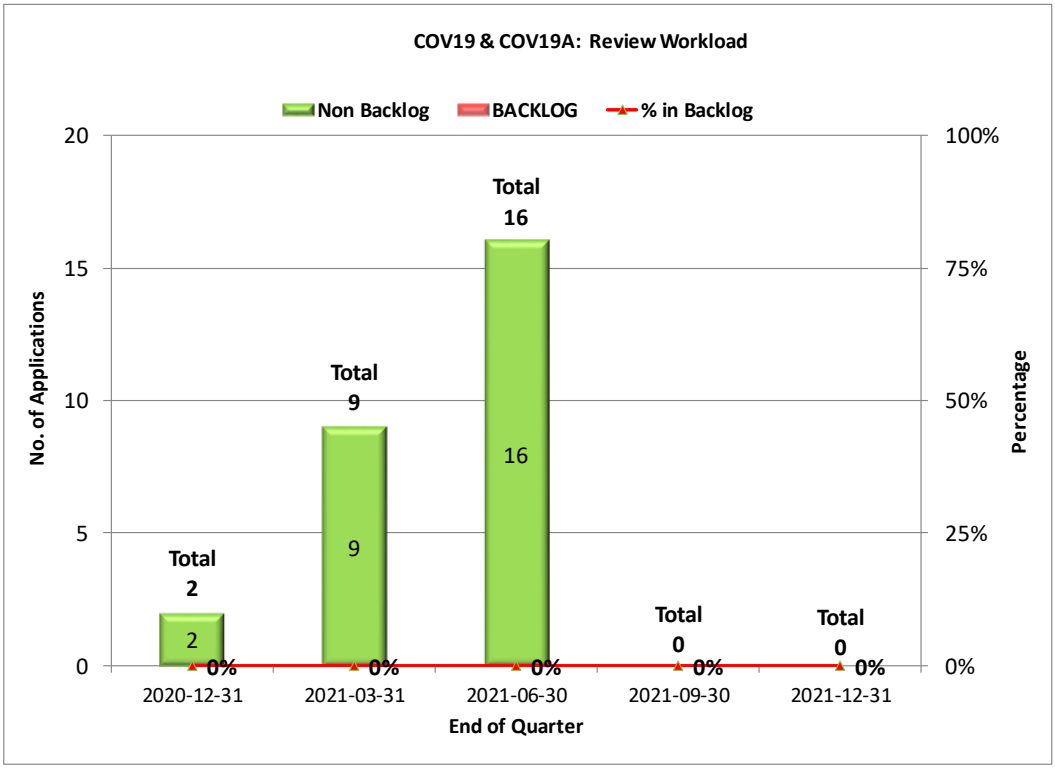
RECEIVED

COV19 & COV19A: Number Received



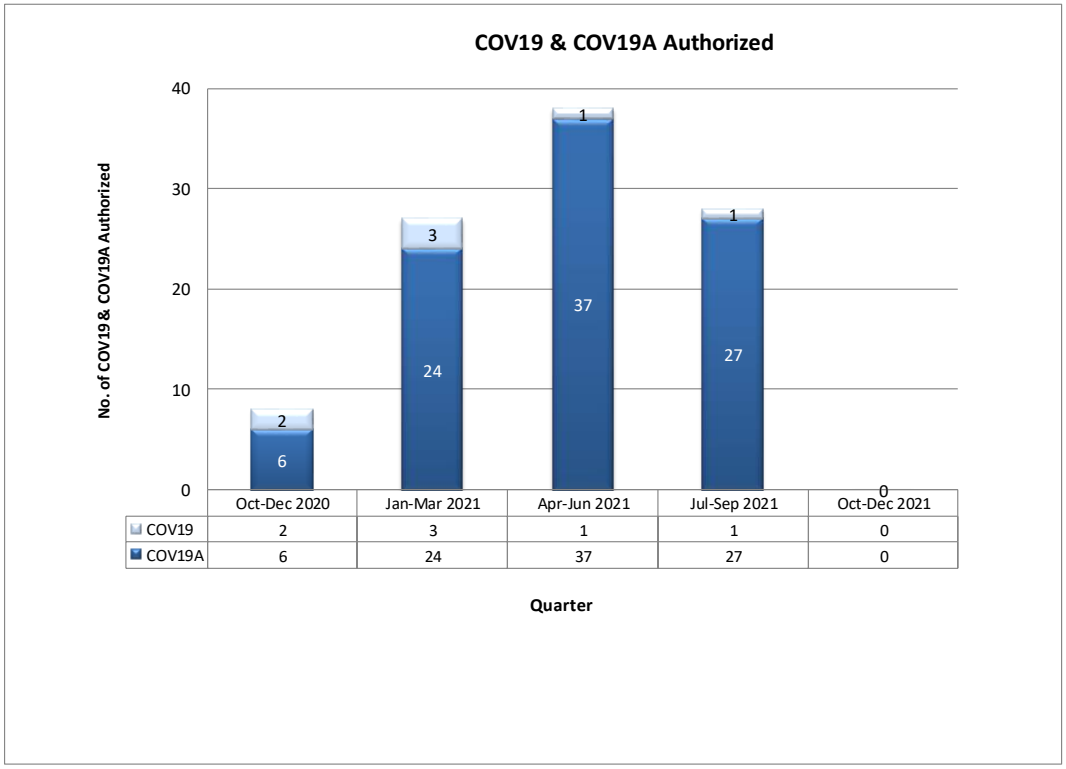
WORKLOAD

COV19 & COV19A: Review Workload



AUTHORIZATIONS

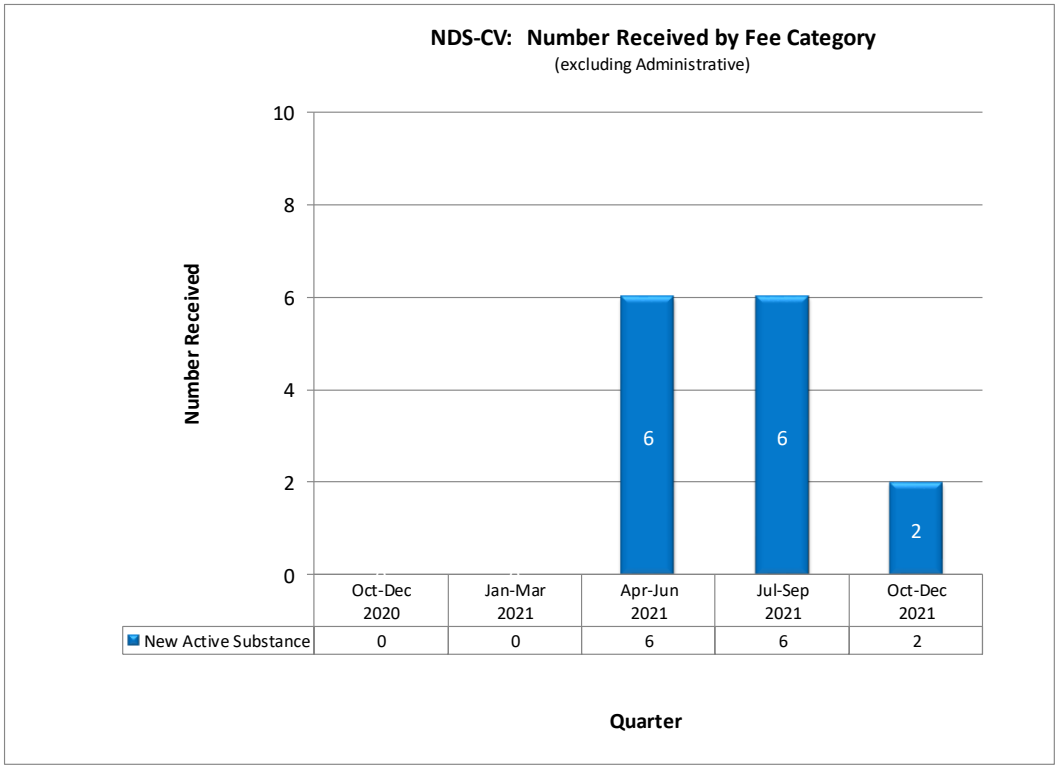
COV19 & COV19A: Number Authorized



New Drug Submissions for Designated COVID-19 Drugs (NDS-CV)

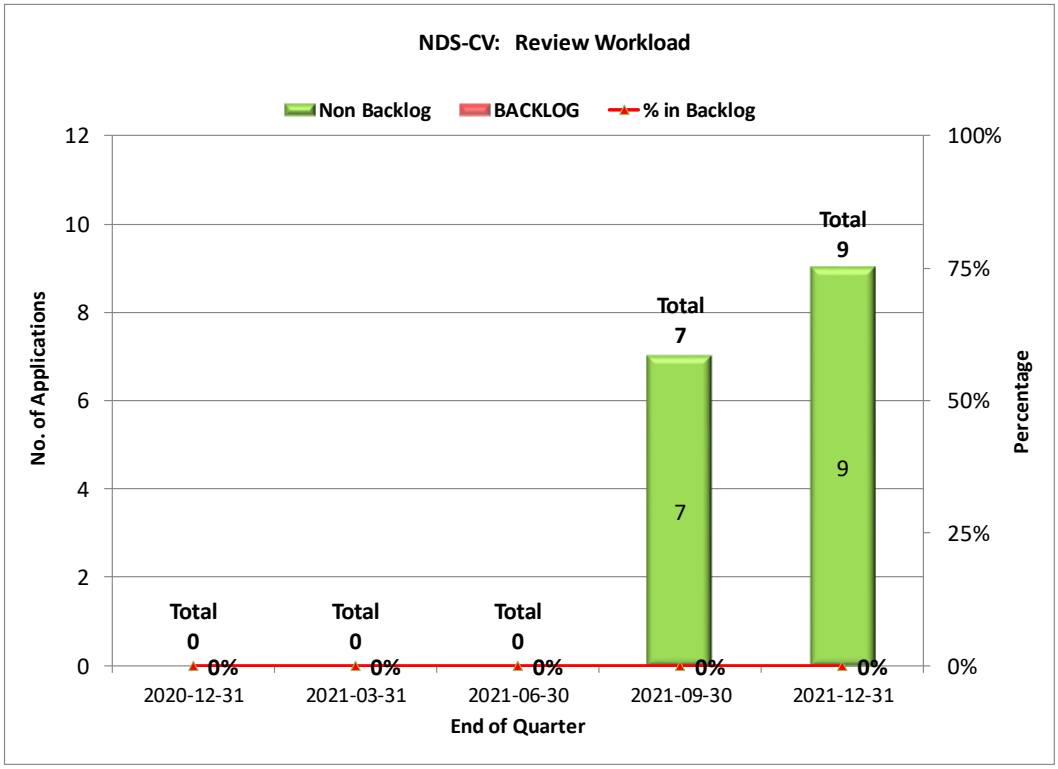
RECEIVED

NDS-CV: Number Received



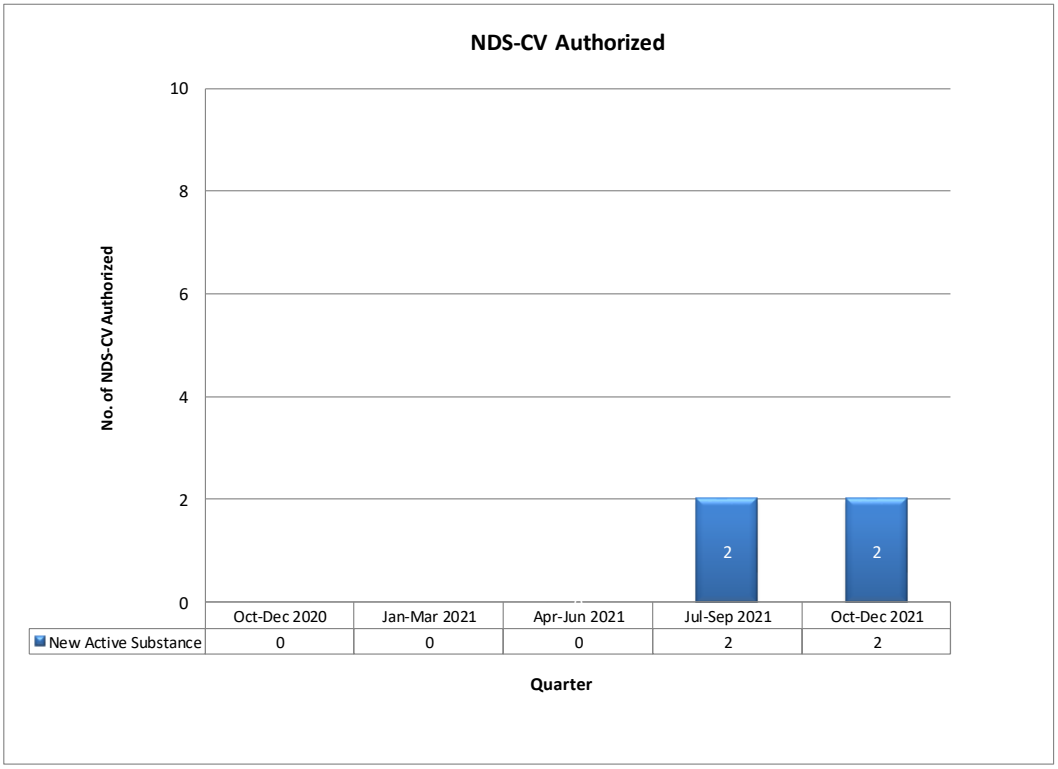
WORKLOAD

NDS-CV: Review Workload



AUTHORIZATIONS

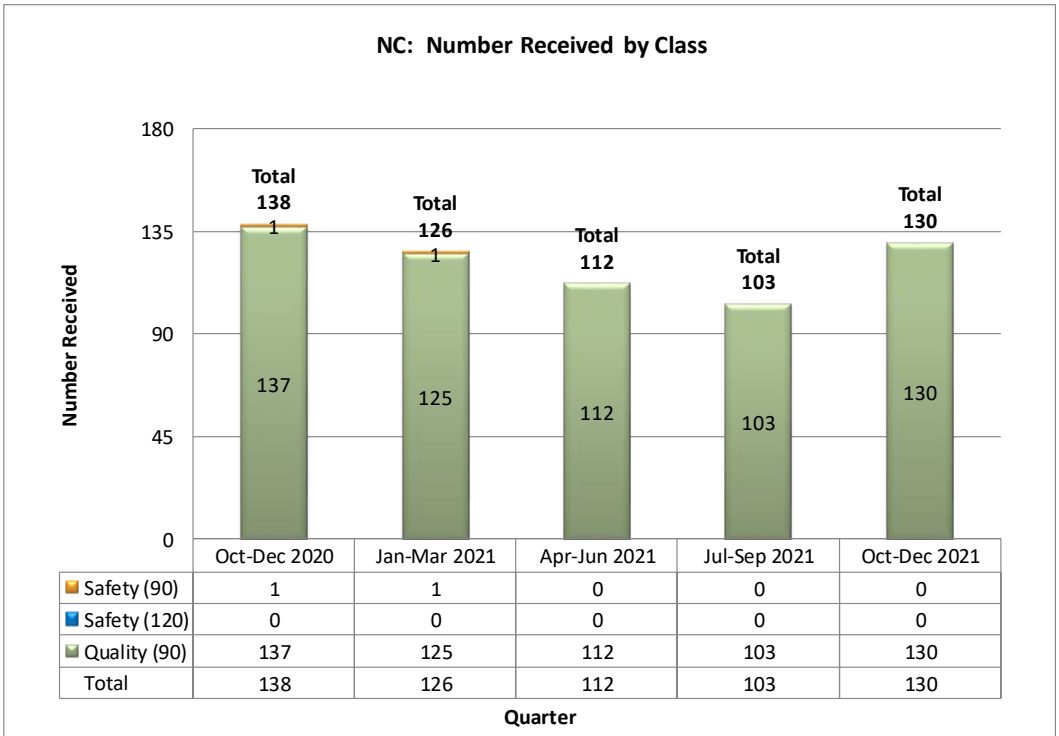
NDS-CV: Number Authorized



NC: NOTIFIABLE CHANGE

NC: NOTIFIABLE CHANGE

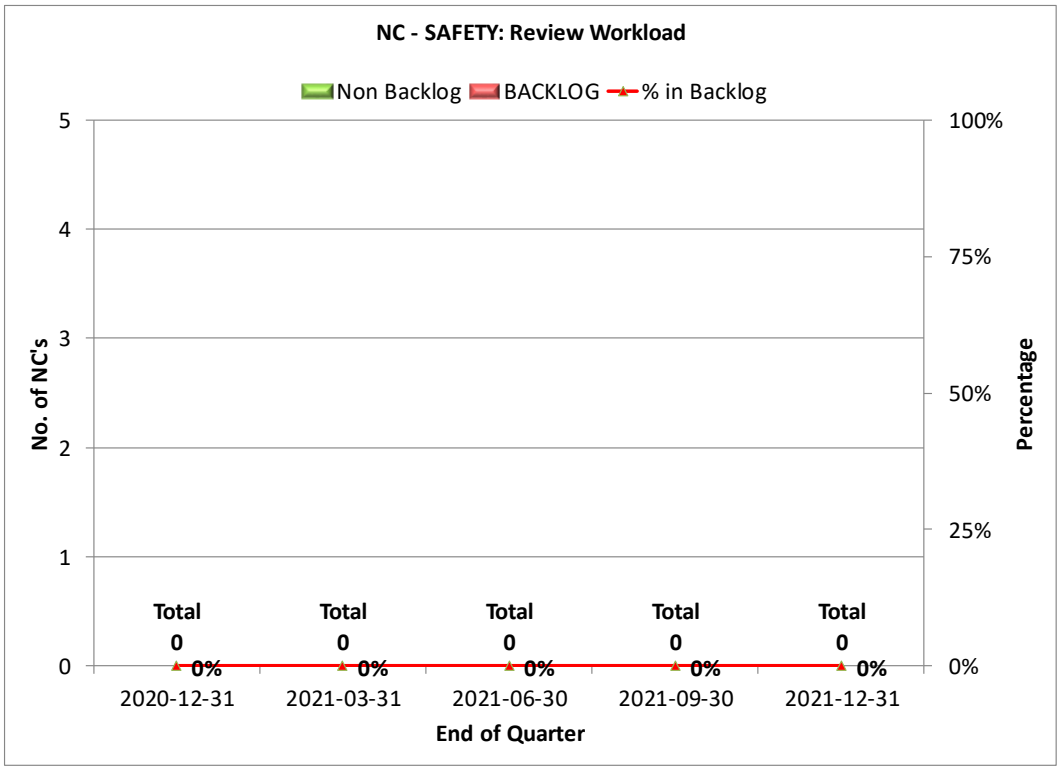
NC: Number Received by Class



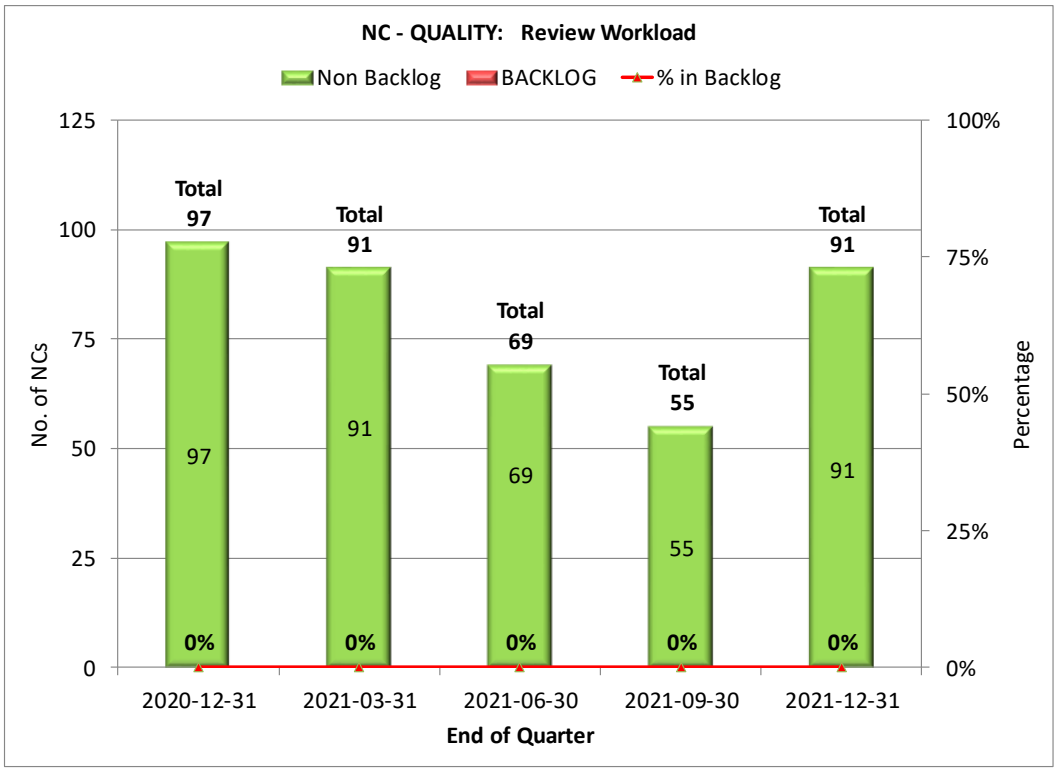
	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Safety (90)	1	1	0	0	0
Safety (120)	0	0	0	0	0
Quality (90)	137	125	112	103	130
Total	138	126	112	103	130

WORKLOAD

NC-SAFETY: Review Workload



NC-QUALITY: Review Workload



WORKLOAD

NC-SAFETY: Review Workload by Class

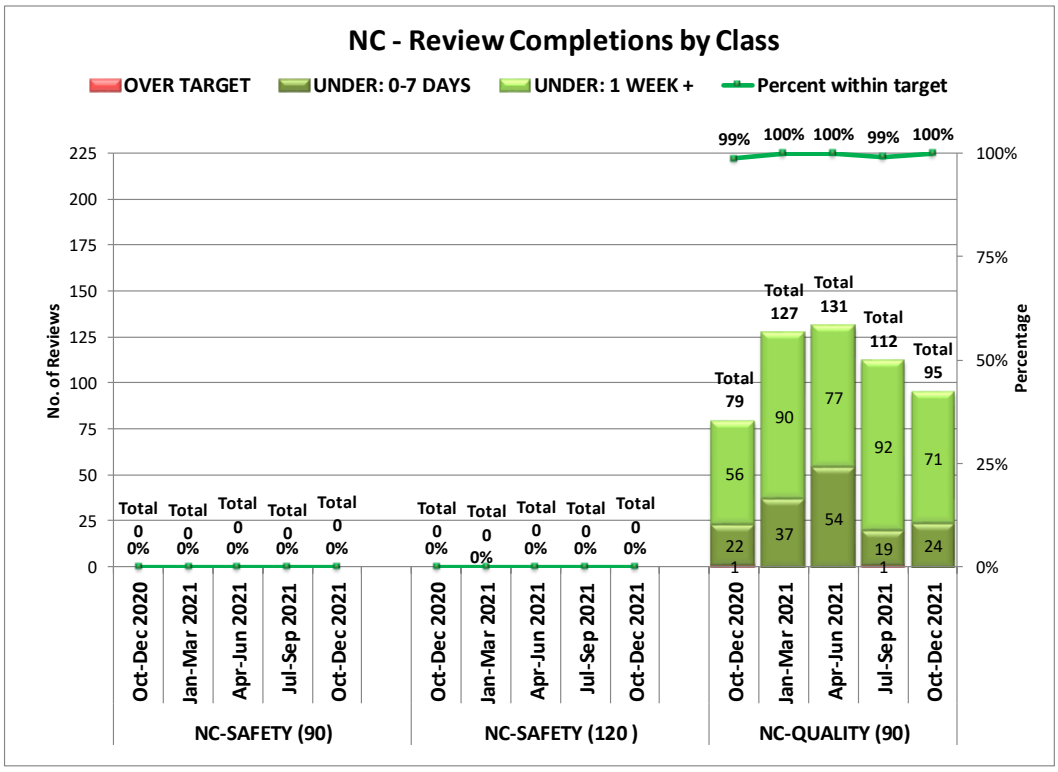
BRDD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
SAFETY - 90 day	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	0	0	0	0	0
Non Backlog	0	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC-QUALITY: Review Workload by Class

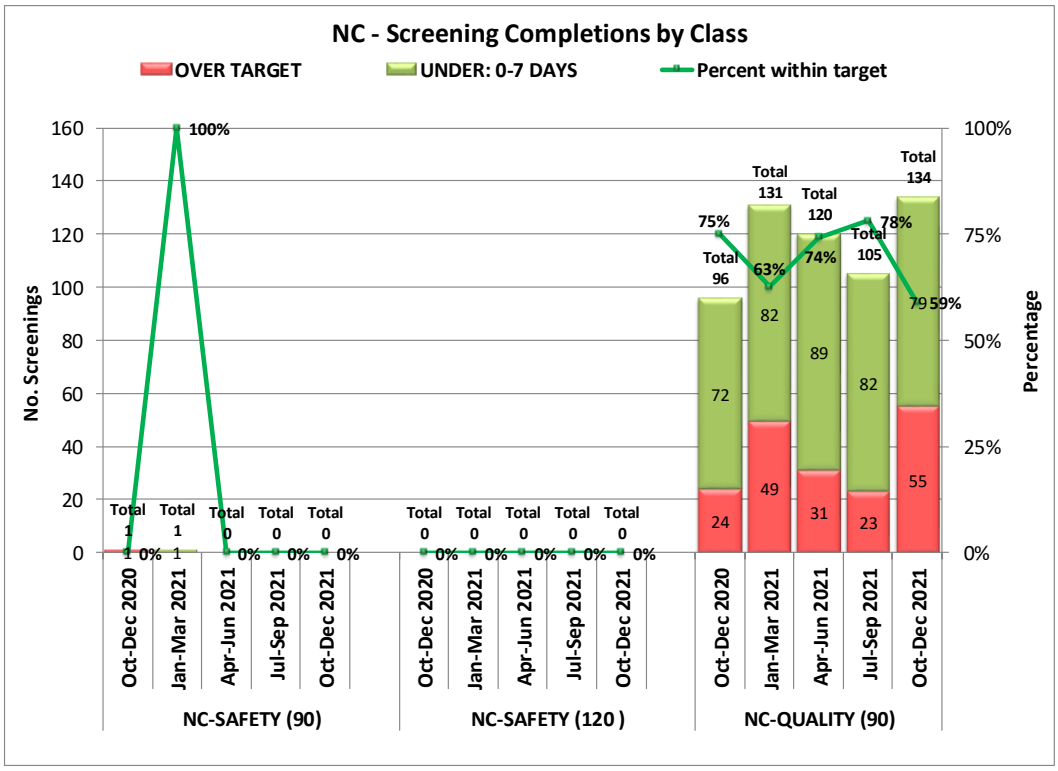
BRDD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
QUALITY - 90 day	97	91	69	55	91
Backlog	*0*	*0*	*0*	*0*	*0*
Total	97	91	69	55	91
Non Backlog	97	91	69	55	91
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NC: Review Completions by Class



NC: Screening Completions by Class



NC: Decision Documents by Class

NC - SAFETY (90)					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
NO OBJECTION LETTER	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	1	1	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

NC - QUALITY (90)					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
NO OBJECTION LETTER	133	133	136	97	95
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	1	0	5	8	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	12	4	1	14	3
NC - HOLD (PATENT)	0	0	0	0	0

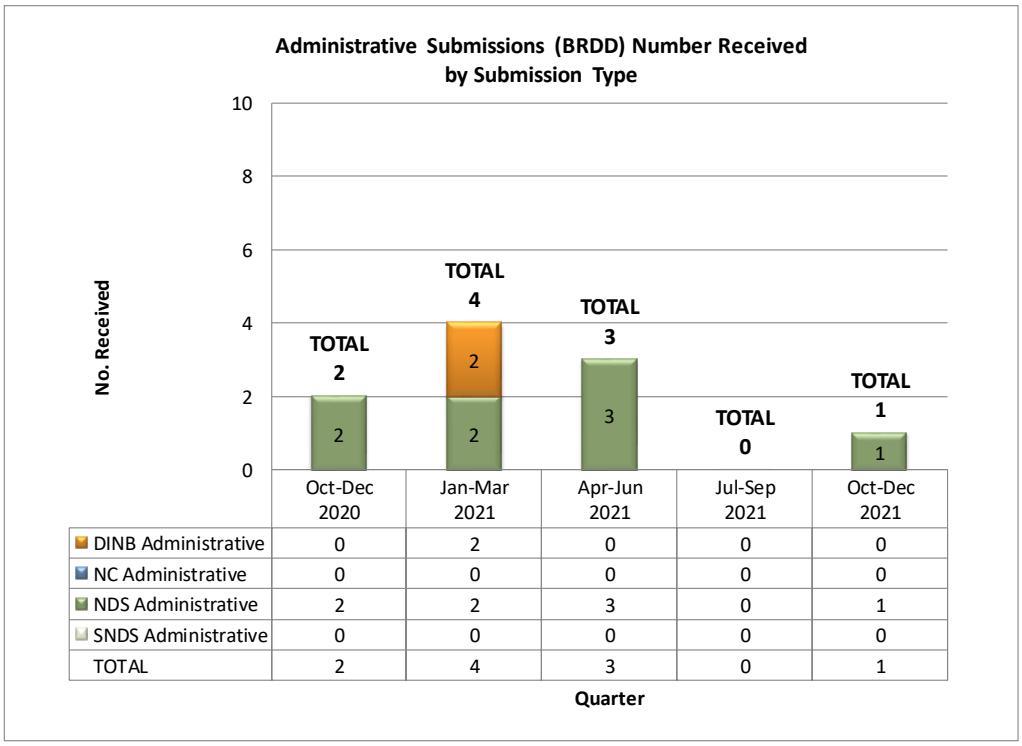
NC - SAFETY (120)					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
NO OBJECTION LETTER	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

NC - ADMINISTRATIVE					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
NO OBJECTION LETTER	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS (Processed by BRDD)

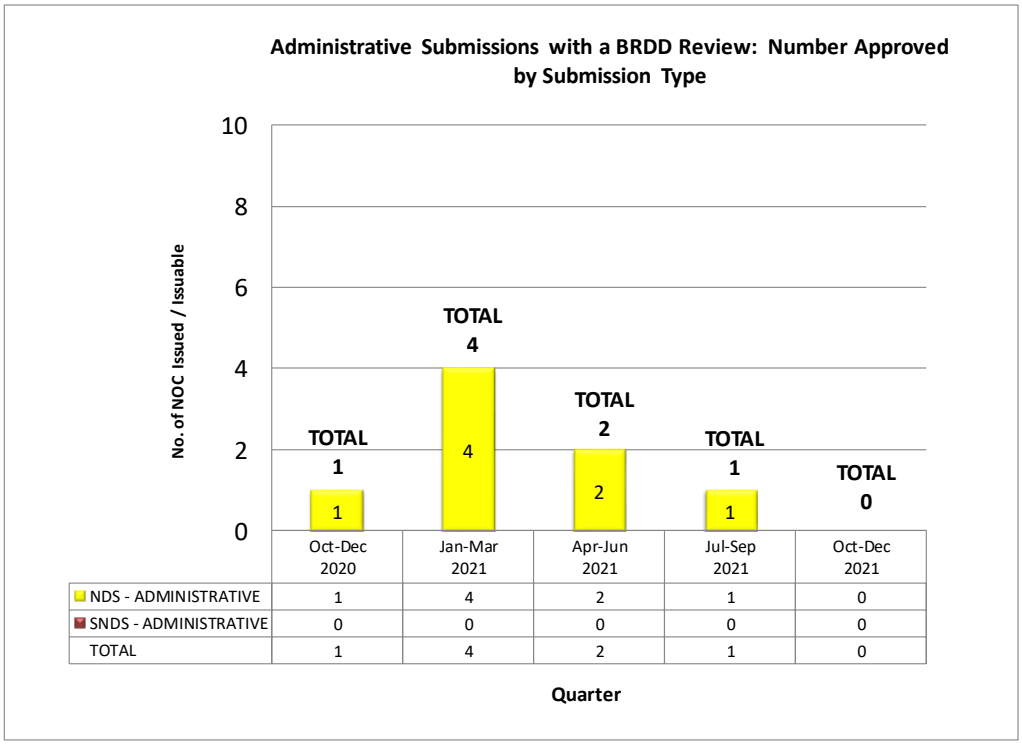
(e.g. product name changes that require a drug name review)

Administrative Submissions (with BRDD Review): Number Received



	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
DINB Administrative	0	2	0	0	0
NC Administrative	0	0	0	0	0
NDS Administrative	2	2	3	0	1
SNDS Administrative	0	0	0	0	0
TOTAL	2	4	3	0	1

Administrative Submissions (with BRDD Review): Number Approved



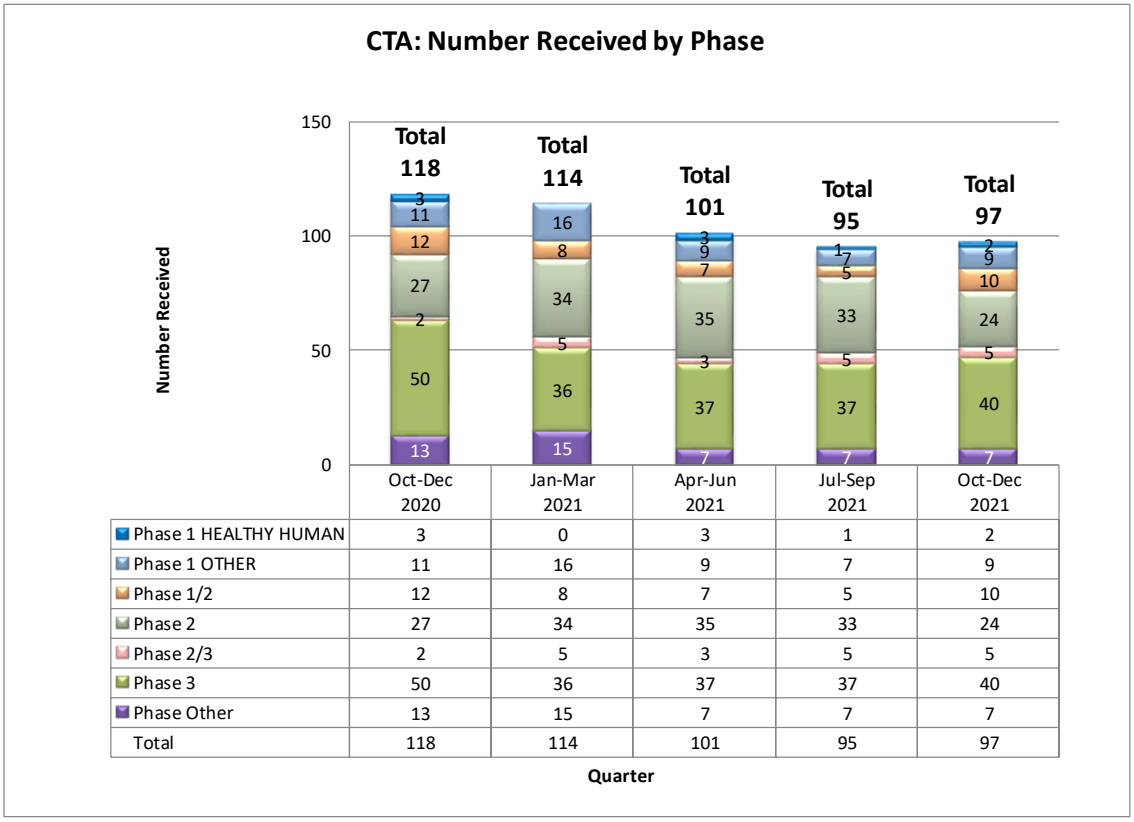
	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
NDS - ADMINISTRATIVE	1	4	2	1	0
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	1	4	2	1	0

CLINICAL TRIAL APPLICATIONS AND AMENDMENTS

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS (CTA)

CTA: Number Received by Phase

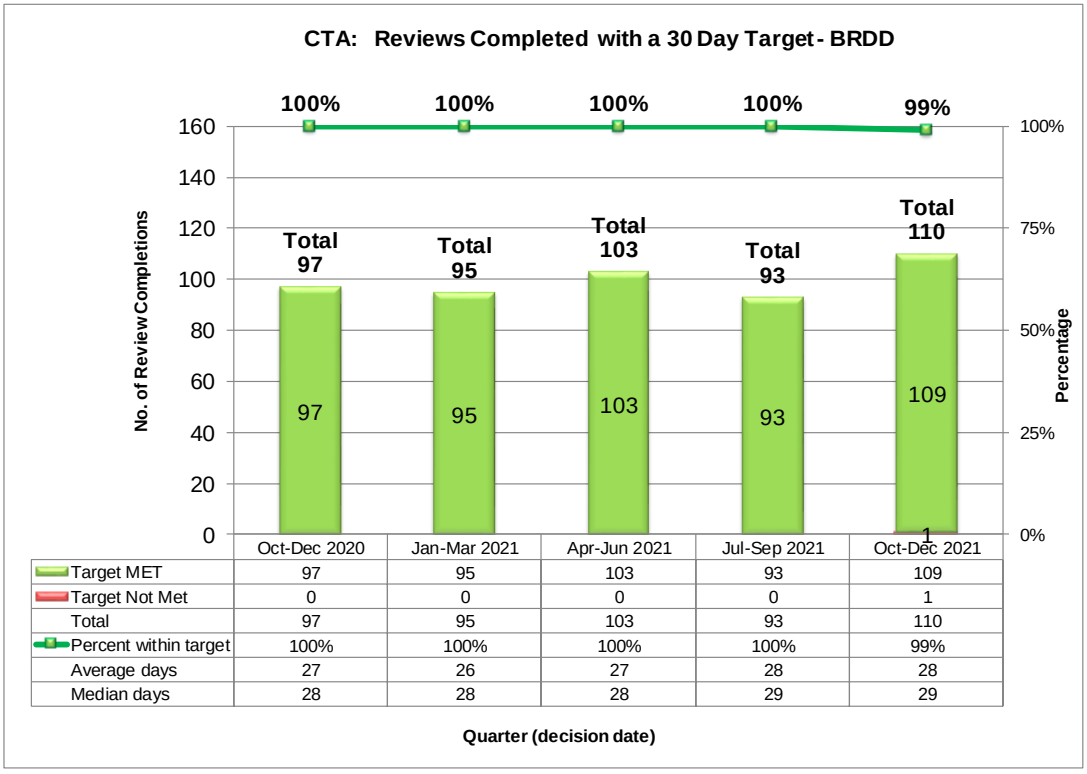


	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Phase 1 HEALTHY HUMAN	3	0	3	1	2
Phase 1 OTHER	11	16	9	7	9
Phase 1/2	12	8	7	5	10
Phase 2	27	34	35	33	24
Phase 2/3	2	5	3	5	5
Phase 3	50	36	37	37	40
Phase Other	13	15	7	7	7
Total	118	114	101	95	97

CTA: Number of Decisions by Document Type

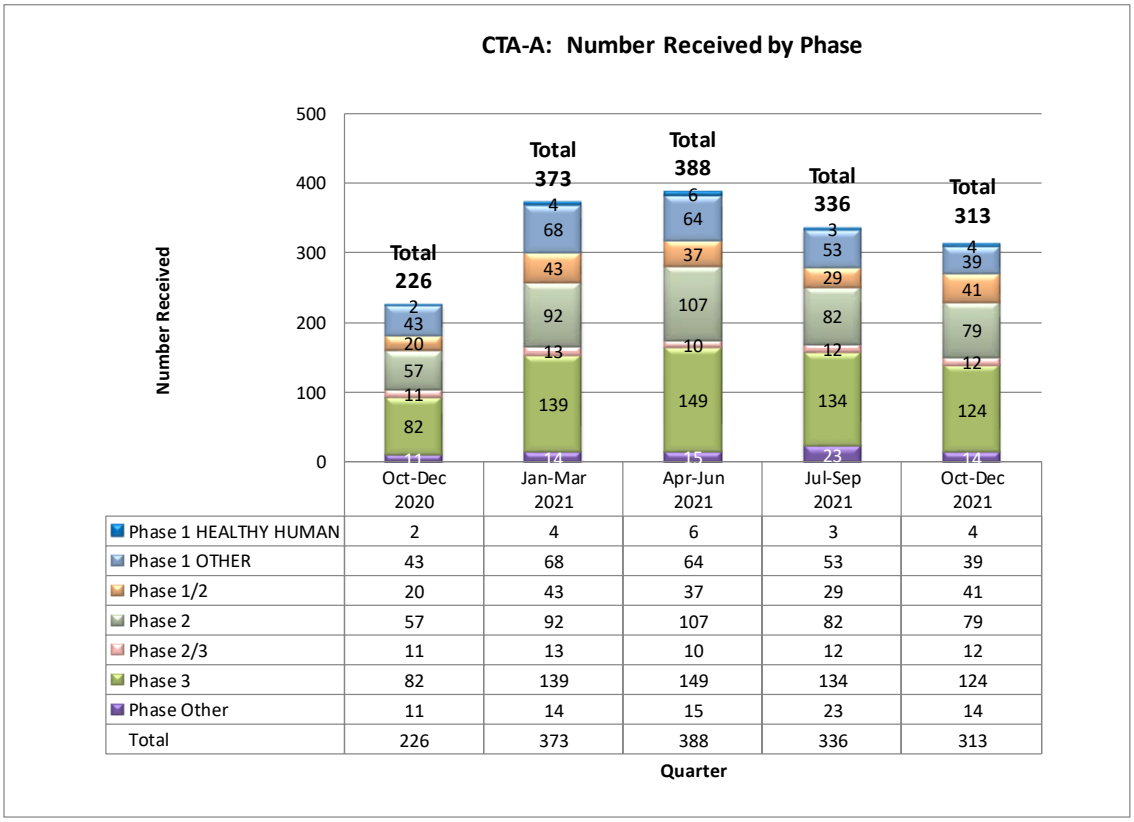
CTA					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
NO OBJECTION LETTER	115	85	100	91	104
CANCELLED BY COMPANY DURING REVIEW	7	7	3	2	5
CANCELLED BY COMPANY AT PROCESSING	2	2	1	1	1
REJECTION LETTER (SCR)	1	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NOTICE OF AUTHORIZATION	7	3	4	3	2
NOTICE OF AUTHORIZA/ TC	0	0	1	1	1

CTA: Review Completed with a 30 Day Target



CLINICAL TRIAL APPLICATION- AMENDMENTS (CTA-A)

CTA-A: Number Received by Phase

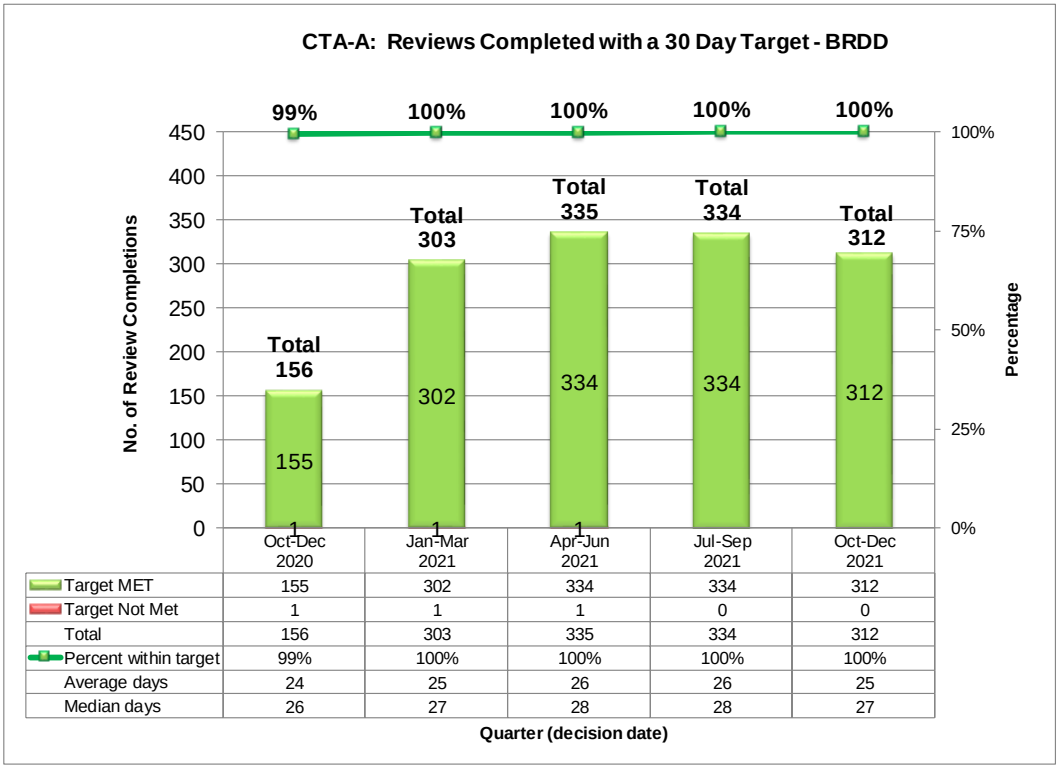


	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Phase 1 HEALTHY HUMAN	2	4	6	3	4
Phase 1 OTHER	43	68	64	53	39
Phase 1/2	20	43	37	29	41
Phase 2	57	92	107	82	79
Phase 2/3	11	13	10	12	12
Phase 3	82	139	149	134	124
Phase Other	11	14	15	23	14
Total	226	373	388	336	313

CTA-A: Decisions by Type

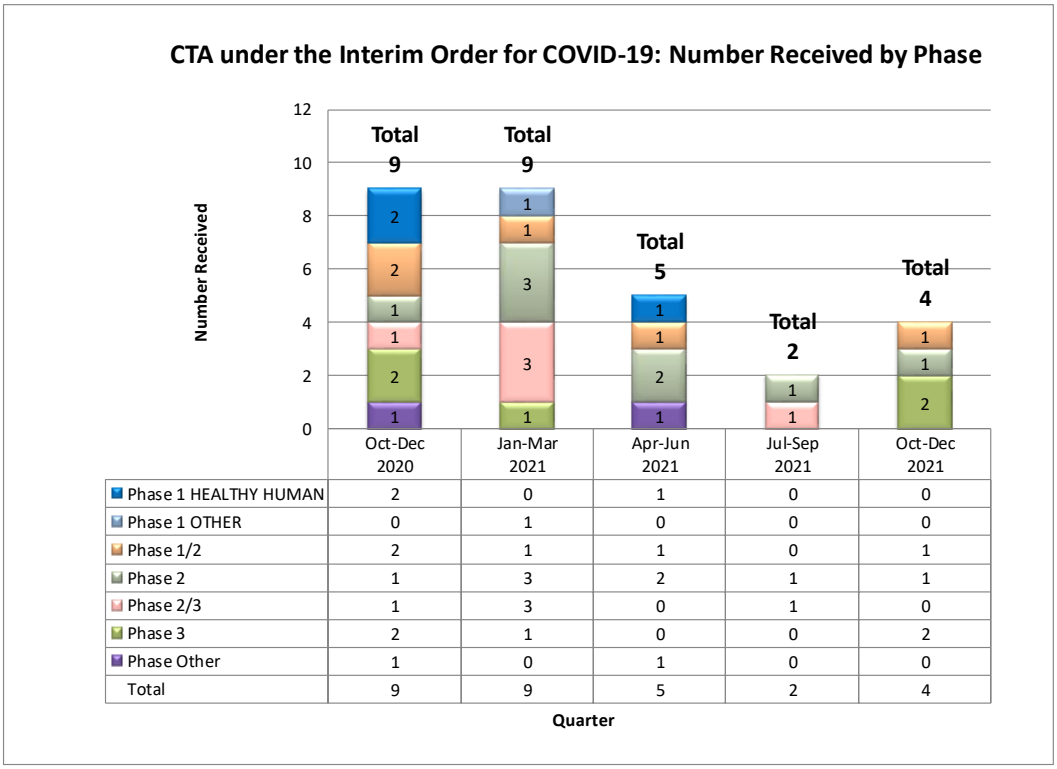
CTA-A					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
NO OBJECTION LETTER	250	294	351	346	331
REJECTION LETTER (SCR)	5	2	9	2	6
CANCELLED BY COMPANY DURING REVIEW	1	7	3	4	2
CANCELLED BY COMPANY AT PROCESSING	3	2	0	3	5
NOTICE OF AUTHORIZ A/TC	0	0	0	0	1
NOTICE OF AUTHORIZA/ TC	0	0	0	0	1
NOTICE OF AUTHORIZATION	4	10	14	11	10

CTA-A: Reviews Completed with a 30 Day Target



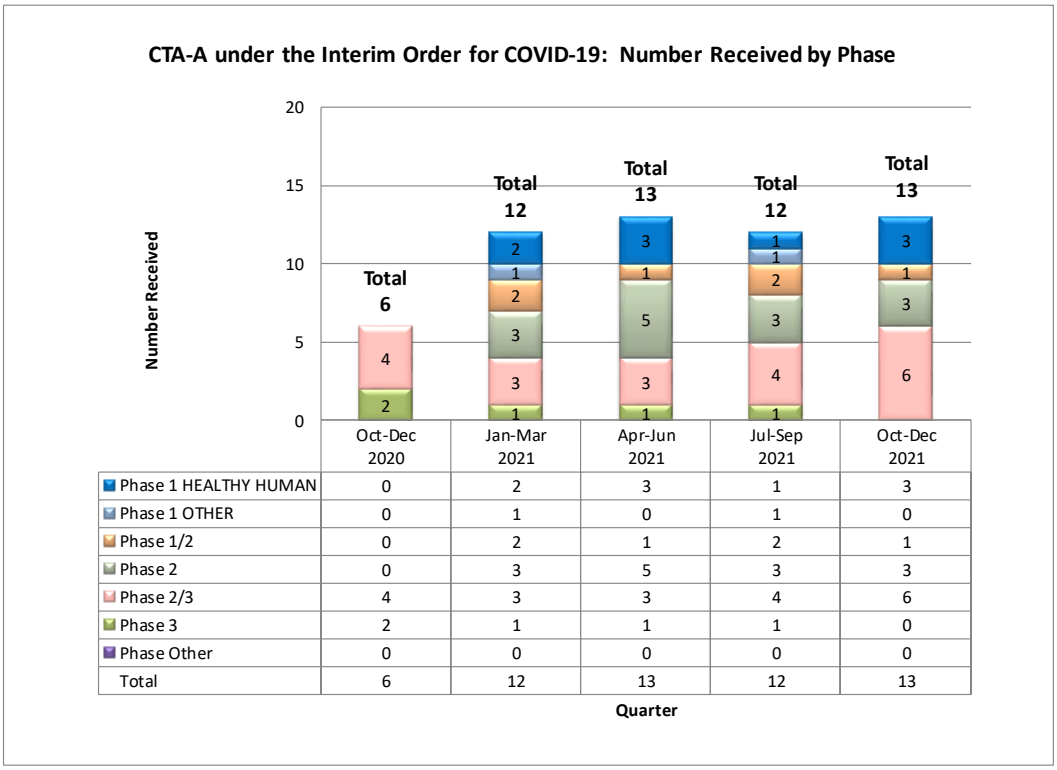
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID-19

CTA: Number Received under the Interim Order Covid-19 by phase



	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Phase 1 HEALTHY HUMAN	2	0	1	0	0
Phase 1 OTHER	0	1	0	0	0
Phase 1/2	2	1	1	0	1
Phase 2	1	3	2	1	1
Phase 2/3	1	3	0	1	0
Phase 3	2	1	0	0	2
Phase Other	1	0	1	0	0
Total	9	9	5	2	4

CTA-A: Number Received under the Interim Order Covid-19 by phase

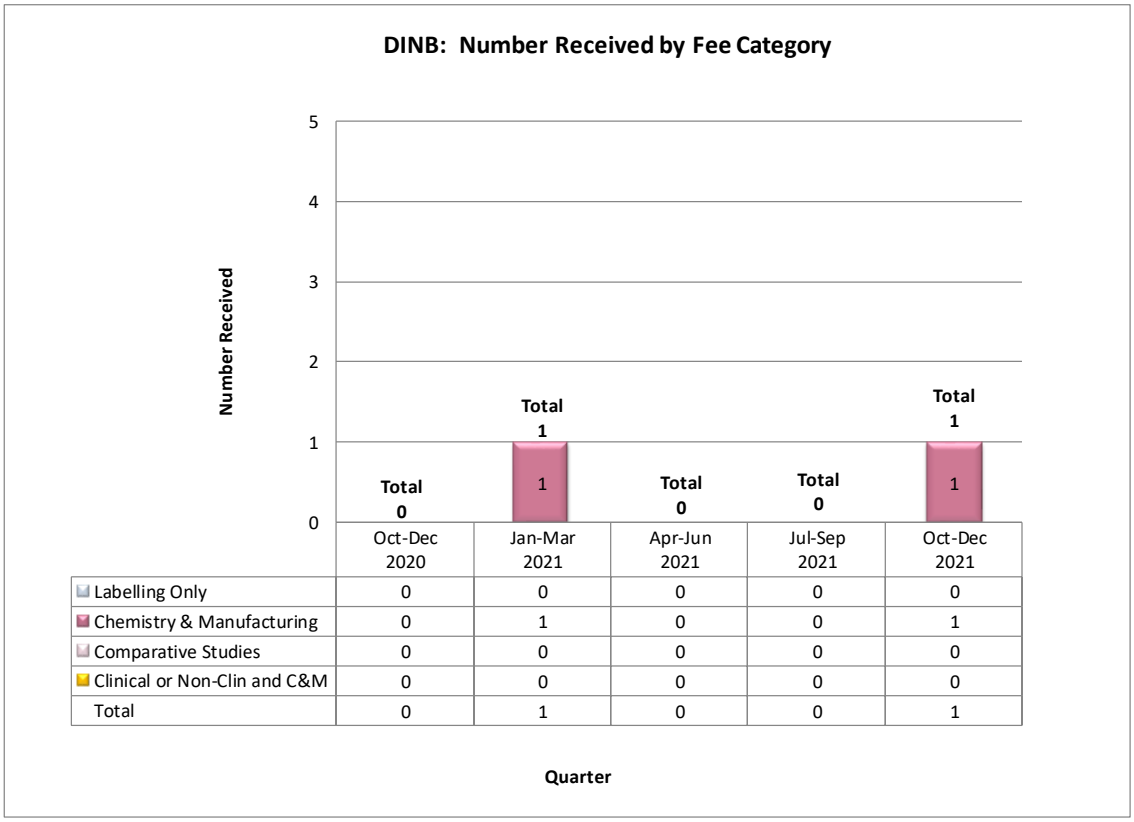


	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Phase 1 HEALTHY HUMAN	0	2	3	1	3
Phase 1 OTHER	0	1	0	1	0
Phase 1/2	0	2	1	2	1
Phase 2	0	3	5	3	3
Phase 2/3	4	3	3	4	6
Phase 3	2	1	1	1	0
Phase Other	0	0	0	0	0
Total	6	12	13	12	13

These figures are a subset of the total CTA and CTA-A received.

DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

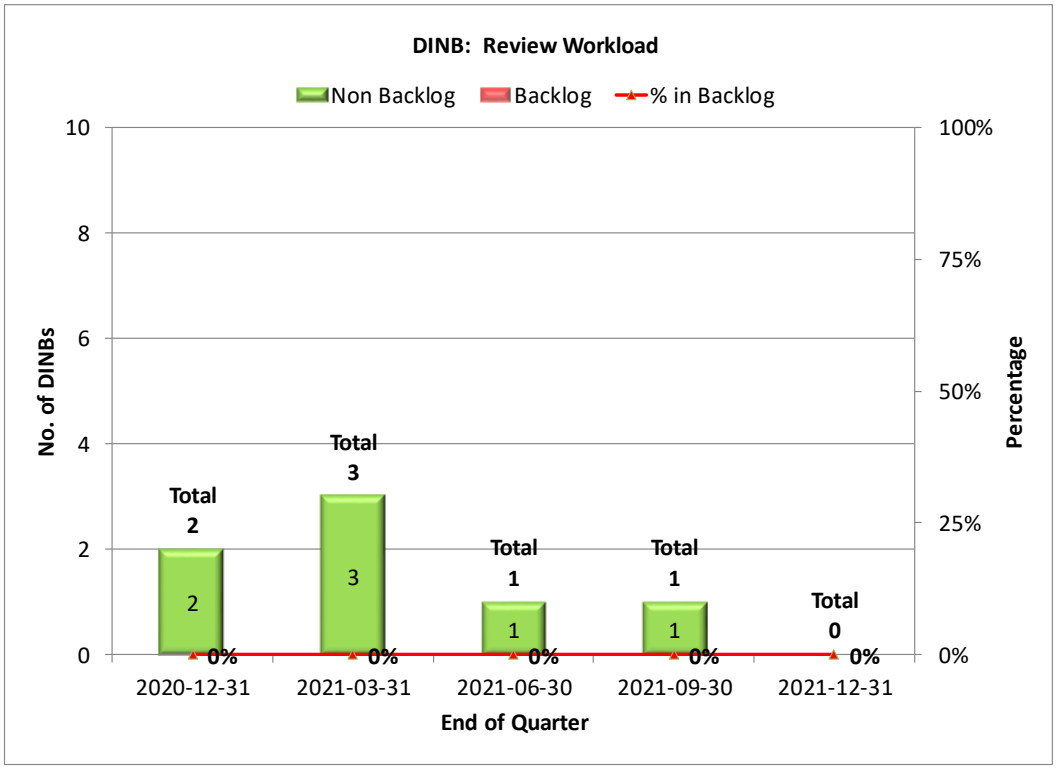
DINB: Number Received by Fee Category



	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Labelling Only	0	0	0	0	0
Chemistry & Manufacturing	0	1	0	0	1
Comparative Studies	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	0	0	0
Total	0	1	0	0	1

REVIEW WORKLOAD

DINB: Review Workload

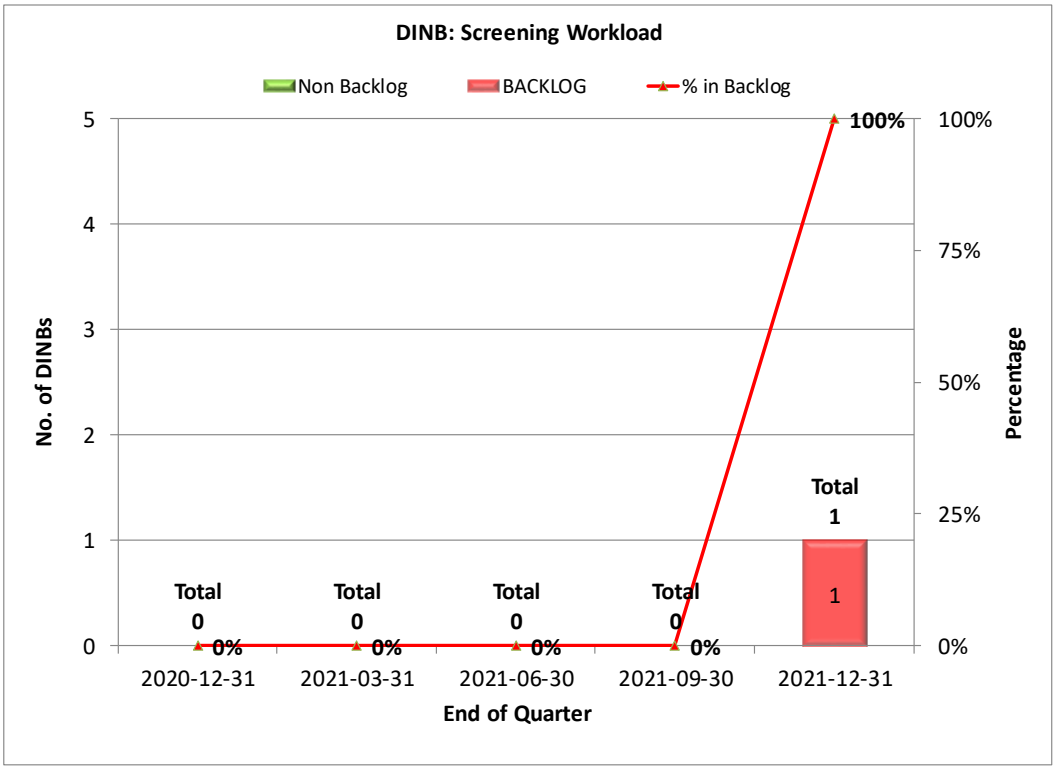


DINB: Review Workload by Fee Category

DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Labelling Only	0	1	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	2	2	1	1	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	2	3	1	1	0
Non Backlog	2	3	1	1	0
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SCREENING WORKLOAD

DINB: Screening Workload



DINB: Screening Workload by Fee Category

DINB: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-12-31	2021-03-31	2021-06-30	2021-09-30	2021-12-31
Labelling Only	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	0	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	0	0	0	0	1
Backlog	*0*	*0*	*0*	*0*	*1*
Total	0	0	0	0	1
Non Backlog	0	0	0	0	0
BACKLOG	0	0	0	0	1
% in Backlog	0%	0%	0%	0%	100%

DECISIONS

DINB: Number of Decisions by Fee Category

DINB - LABELLING ONLY					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
DINB APPROVAL LETTER	11	1	2	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	2	0	0	0	0
NOTICE OF DEFICIENCY	2	0	0	0	0

DINB - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

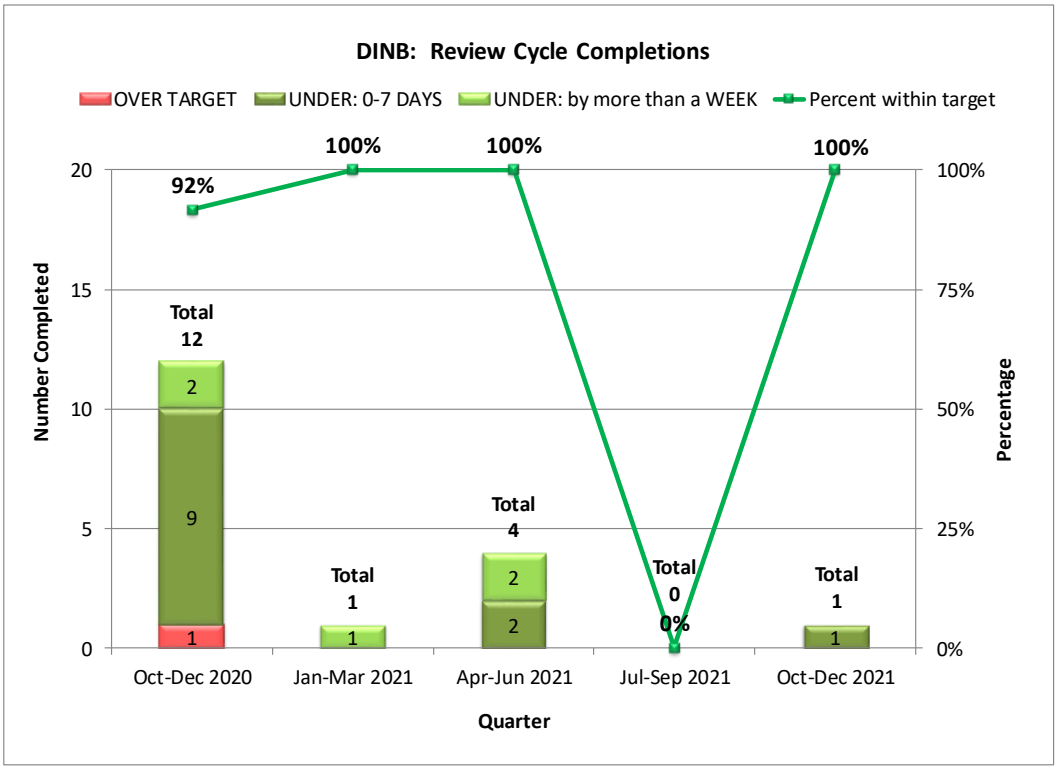
DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
DINB APPROVAL LETTER	0	0	2	0	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

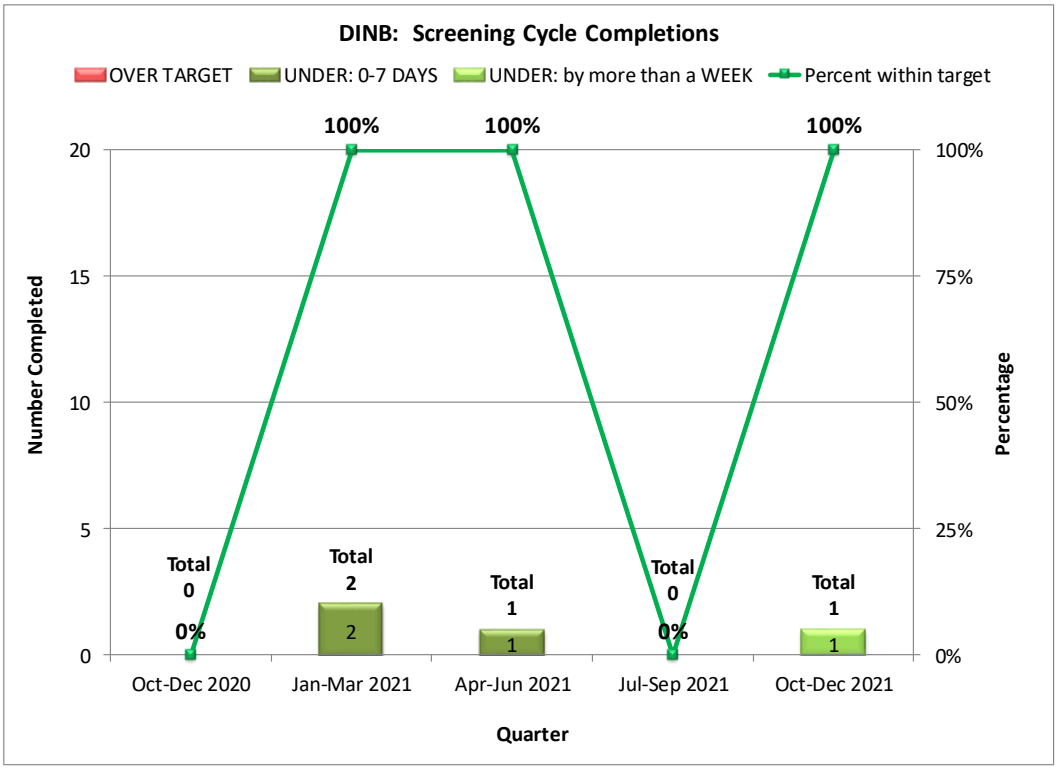
DINB - Administrative					
DOCUMENT TYPE	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**	**Jul-Sep 2021**	**Oct-Dec 2021**
DINB APPROVAL LETTER	0	2	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

PERFORMANCE

DINB: Review Cycle Completions

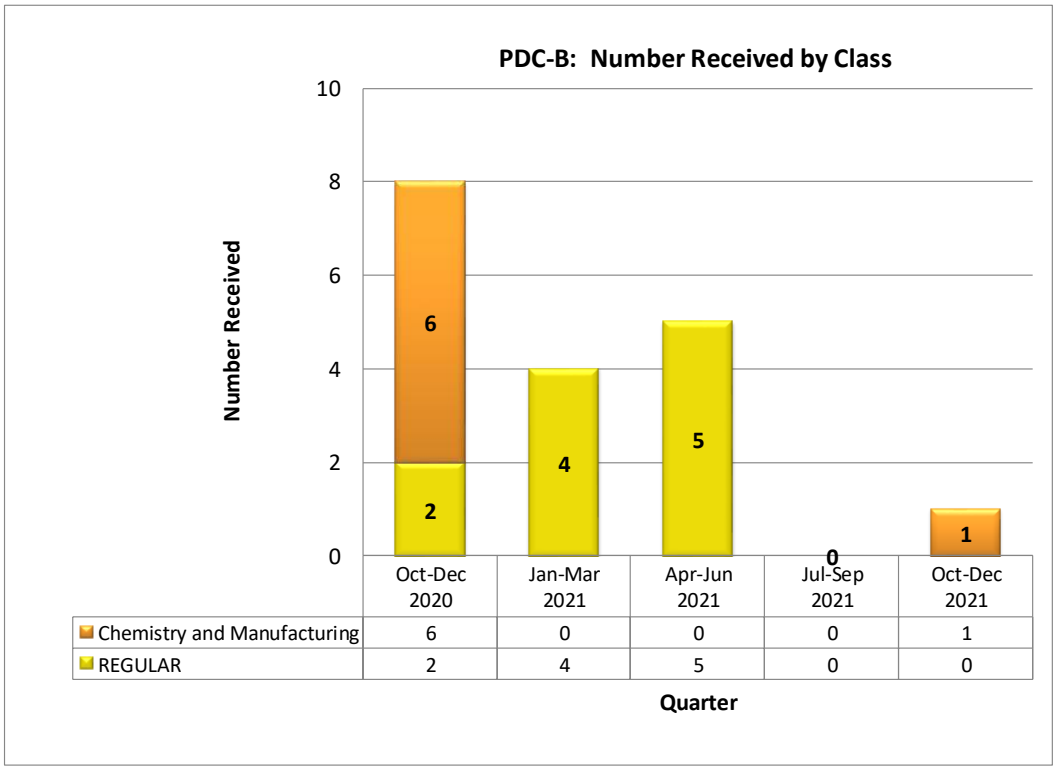


DINB: Screening Cycle Completions



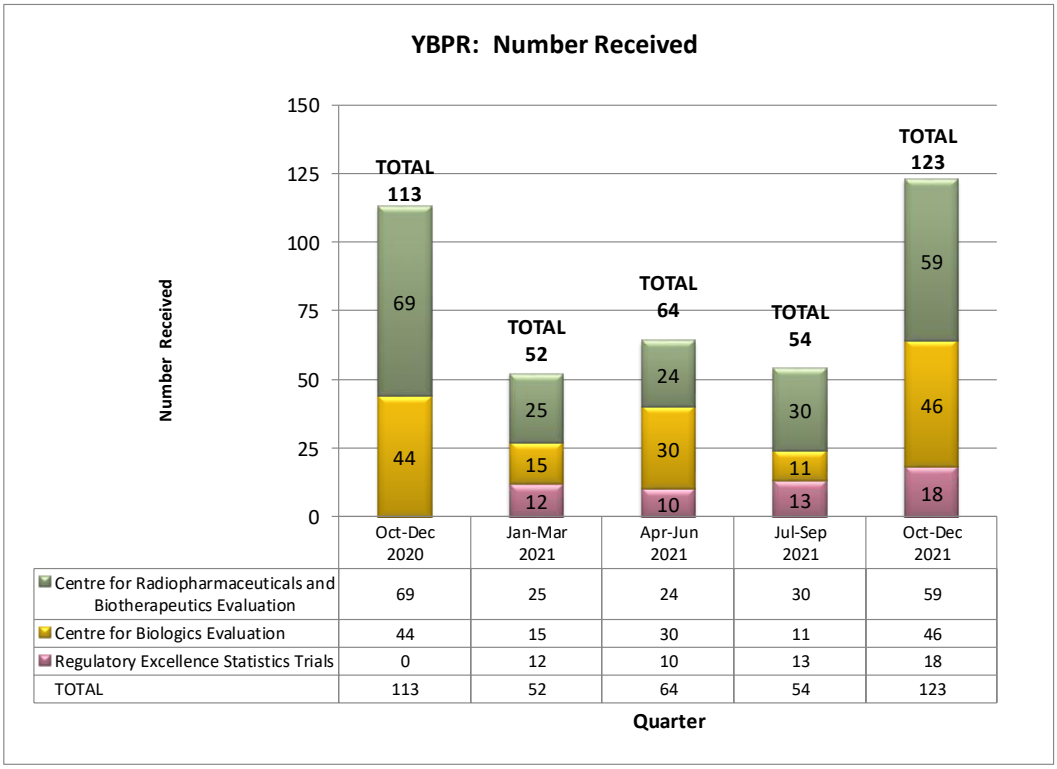
POST-AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT (PDC-B)

PDC-B: Number Received



YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) [9]

YBPR: Number Received

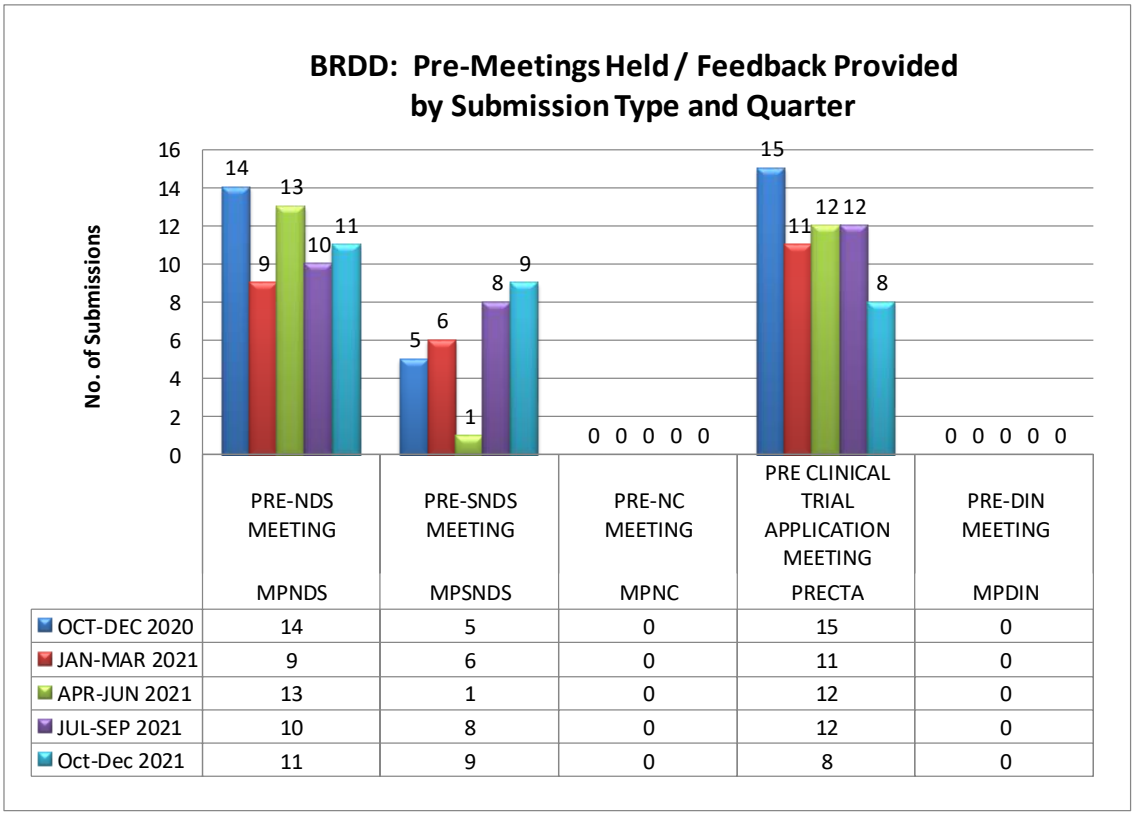


	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	69	25	24	30	59
Centre for Biologics Evaluation	44	15	30	11	46
Regulatory Excellence Statistics Trials	0	12	10	13	18
TOTAL	113	52	64	54	123

[9] Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

APPENDIX A: PRE-SUBMISSION MEETINGS [10]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-NC MEETING MPNC	PRE CLINICAL TRIAL APPLICATION MEETING PRECTA	PRE-DIN MEETING MPDIN
OCT-DEC 2020	14	5	0	15	0
JAN-MAR 2021	9	6	0	11	0
APR-JUN 2021	13	1	0	12	0
JUL-SEP 2021	10	8	0	12	0
Oct-Dec 2021	11	9	0	8	0

[10] Prior to filing a submission, the sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the Guidance for Industry: Management of Drug Submissions.